To those of you who have been serving on this committee since it's formation, this will probably sound trite, but the emotional issue of Agent Orange is by far the most frustrating problem I'm facing in my new role in the Federal government.

I've been quoted in the news media on Agent Orange and judging from the reaction, some people have assumed that I have made up my mind on the subject. I wish that that were true. I wish it were possible. I wish the facts were available that would allow reasonable people to say that exposure to Agent Orange in Vietnam does have a direct cause and effect relationship to the current and future health of veterans. Or that the facts would let us in good conscience reassure those veterans and their families that they have nothing to fear from their experiences. But based on what I have learned about your past proceedings and from other scientific sources it appears that we are not yet in a position to take either of those courses. And for that reason I remain committed to pursuing scientific inquiry on this subject until a reasonable and medically supportable solution can be found.

Until the facts are known that will either establish that elusive link or somehow accomplish the impossible feat of proving a negative, VA remains in the middle. We can't make compensation awards on the basis of self-diagnosis. In short, we are completely dependent on the scientific community for our course of action. We have no independent position on Agent Orange anymore than we do on any other medical or scientific subject. In all areas VA seeks to deal with medical problems on the basis of the latest validated medical information.

For that reason I was pleased when I learned that through this body the basic machinery had been set up to allow VA to not only catch up but to keep up in an area that is relatively new to the agency, the field of environmental medicine. With your help, VA has come a long way during the three years or so since this issue surfaced. There is still another way you can help. As individuals with great credibility in scientific areas, you can help veterans and news media understand what is known about Agent Orange. Obviously, the many studies now underway need to be

completed before we have all the answers but it does seem to me that as a layman you have already established a solid base for correcting some of the misinformation that continues to be circulated.

I'll avoid getting too specific rather than run the risk of exposing you to some of this layman's interpretations. I ask only that you set the records straight whenever or wherever you see many of the exaggerations and distortions of this subject. I believe our responsibility to relieve unfounded anxiety among veterans and their families, is at least equal to our responsibility to press on for whatever final answers there might be.

There are many people who are sincerely and deeply concerned about Agent Orange who could get a measure of relief from anxiety by knowing facts and perspectives which you can provide. On behalf of those individuals I urge you to speak out when you consider it appropriate and to encourage your fellow scientists to do the same. You have my sincere gratitude and my hopes for a successful meeting.

DR. SHEPARD: As I said Mr. Nimmo regretted not being able to be here, and hopefully, he will be able to address the committee and those in the audience at future meetings. I think you could tell from his words that he is committed to a sound scientific approach to this issue and, at the same time, to addressing the concerns of veterans in a variety of ways in which those concerns are raised.

A few other housekeeping notes. We would like all visitors to register in the outer room. Any of you who have questions, if you would please submit those in writing, we have a portion of the agenda devoted to receiving your questions and making the committee available for comment on those questions.

Many of you, I hope most of you have seen our audiovisual tape, "Agent Orange, A Search for Answers". I'm very pleased to announce that it has received two outstanding awards. The Health Education Communication Association presented an outstanding achievement award for the use of television for education and the health sciences, and the International Television Association awarded its Golden Reel of Excellence Citation for the videotape's highly effective form of communication which help the user organization better achieve

its stated goals. So we are pleased to acknowledge the awards that this tape has received, and I hope that those of you who have not seen it will avail yourselves an opportunity to do so.

At this time, I'd like to address the issue of our epidemiological study about which Dr. Hobson will make further comment. First, I'd just like to state a few of the ground rules in which we plan to deal with the draft design of the VA epidemiological study, mandated by Public Law 96-151. We now have the proposed design. Copies have been circulated to members of the committee. We would like the members of the committee to submit to us your written comments, suggestions, anything that you feel needs to be changed or whatever on the design. If you would please submit those to me in writing no later than the end of September. That is, the 30th of September, please try to have them in my office no later than the 30th of September. If you can make it earlier than that, we would very much appreciate that because, as I'm sure you are aware, a lot of attention is being focused on this, and we are anxious to expedite the review process as rapidly as possible consistent with good scientific methodology.

Others of you who have a desire to review the protocol, or I should say the proposed design, and wish a copy of this document, let me say that this is a fairly exhaustive document, and, of necessity, we have had to limit, to some extent, its reproduction, please submit your request to my office, in writing, for a copy of the proposed design. This is in keeping with our commitment to make this document available for public comment, especially from recognized veterans groups, solicit their comments, so that this may be reviewed and incorporated into the final design. I would like to have those written requests for a copy of the design no later than one week from today.

As I say we are on a fairly tight time table. We want to get this review process done as quickly as possible. If you have comments please send them to my office as soon as possible.

I am asking a few members of this committee to help me in synthesizing the comments of the committee and preparing a proposed consensus report for the consideration of the full committee. I think that you would recognize that if we

would ask the committee to act as a committee of the whole to synthesize the comments, it might be burdensome to many of you who come from out-of-town. So if you will please prepare your comments, submit them to me, I will ask a few members of the committee to help me in synthesizing those comments and preparing a committee report, a proposed committee report. The proposed committee report will then be circulated to the committee for their consideration. I hope we can get this all accomplished by the middle of October so that we can then proceed.

I would now like to introduce Dr. Larry Hobson, my clinical associate, who will discuss further some of the highlights of the study.

DR. HOBSON: EPIDEMIOLOGICAL STUDY I'm very glad to be able to discuss this with you this morning. I don't intend to read the entire document as it has some 257 pages. I think, rather, I shall turn to the section that's called "The Outline of the Proposed Study Design".

In introduction I might say that all of us--anyone who has

taken a close look at this problem and the attempt to conduct an epidemiological study--has been struck with the difficulty of determining on an objective basis precisely who was exposed to Agent Orange and who was not. The design of a scientific study in its best form requires that there be objective evidence of exposure and this is what Dr. Spivey, who did the design, has sought very diligently. For reasons beyond his control and that of the the Department of Defense who've been completely cooperative, Dr. Spivey has not been able to gain access to all of the records that could bear on this problem, and therefore, he was unable to determine the extent to which he could document exposure to Agent Orange for a particular individual.

He, therefore, has proposed a design which in essence is a phased study that will yield some information promptly with other information to come on later as the study develops. Now, epidemiologically there are a number of different designs of studies that can be done and he has proposed that there be a cohort study of exposed individuals as opposed to non-exposed individuals, when it is possible to determine the degree of exposure. In evaluating that determination there

would be design and conduct a feasibility study that is simply intended to test whether, in fact, it's possible to determine the level of exposure.

In the meantime, while that is going on, there are other studies that can be done. One is a study of the mortality rate and the causes of death among Vietnam veterans; those who served in Vietnam as opposed to those who were never in Vietnam, those who had combat experience in Vietnam, as best we can determine it, compared to those who did not have combat experience in Vietnam. This will serve two purposes. It may uncover a unique condition and it may focus our attention on certain things that should be taken into consideration in the examination of veterans in the so-called historical cohort study.

In addition to that study of the incidence and cause of death, he proposes that we investigate the causes of disability or of distress that are in the Register which we have been compiling and which now numbers over some 60,000 examined veterans. This again, would be used primarily

to determine whether there is any particular area that should be examined during the course of the cohort study. These pieces of information should be available in something between a year and a year and a half, so that we will have information pertinent to this problem.

You're probably disappointed as I am that we've been unable to define the groups, at least those who were probably most heavily exposed to Agent Orange. On the other hand, I think it is the better part of scientific discretion that we not attempt to design a study until we're certain that we have the facts on which the design can be based.

Now, what is to be done with this design has been explained to you, I'm sure, on numerous occasions but just to review it briefly, it has been submitted to the Office of Technology Assessment, which is a congressional body, and they have put together a panel which is responsible to Congress as well as to us for commenting on this design. We have submitted it also to what is now called the Agent Orange Working Group and which was originally the Interagency Work Group. This group is essentially an executive group created by the President's office, and therefore is in the executive branch of the government.

It includes primarily people in the Federal government. We have submitted it also to the National Academy of the Sciences-National Research Council, which is a non-federal body, and which is composed of the top scientific community in the United States. We have asked them to review this design and comment on it. Besides that, we've submitted it to this Advisory Committee for your comments.

This is probably the most openly and widely reviewed proposal that's ever been made for a design of a study. It will be an interesting experiment to see what comes out of this general review by the public as well as the scientific world.

The conduct of this review is going to be somewhat difficult and time consuming, I am sure, and I would like to introduce Dr. Matthew Kinnard who is in Research and Development here in the VA Central Office. He and I will be handling most of the details of this particular phase of the coordination.

I want to emphasize one other thing before I stop. There is an urgency about this and the longer we take in the review process, the more difficult or the more time consuming the entire study will be. So, I would like to urge that the review of the design be done as expediously as possible.

DR. SHEPARD: Dr. Kinnard asked for a few minutes on the agenda to make what I think is a very interesting announcement.

DR. KINNARD: ANNOUNCEMENT OF RESEARCH SOLICITATION

Thank you Dr. Shepard. As you may have noted, my name does appear on the agenda because what I have to say has just been approved by the Administrator. I am pleased to announce that the Research and Development arm of the VA Central Office has recently taken steps to launch a series of studies designed to investigate the possible long-term health effects of exposure to Agent Orange and Agent Blue.

Specifically, Research and Development (R&D) is soliciting proposals from VA investigators on the biochemical, toxicological, physiological and/or pharmacological aspects of both herbicides. Studies for the most part, the announcement states, should be confined to laboratory animals primarily for two reasons. (1) Since there is already a sizeable investment in the VA Congressionally mandated study

and the Air Force's Ranch Hand study, further studies of these types are unwarranted, and (2) Because of past difficulties in determining whether and to what extent veterans were exposed to the herbicides in Vietnam. Our present plan is to assemble a top flight special review panel to conduct the scientific review. This panel which has yet to be assembled will be composed of representatives from both academia and government. Like all other investigator initiated research proposals, these proposals will be administratively reviewed following scientific review by the appropriate staff of R&D. Unless we encounter some unforeseen delays, awards are expected to be announced in the second quarter of FY 1982. Parenthetically, I'd like to say that when Research and Development made the decision to solicit these proposals we had extensive discussions with Dr. Shepard and his staff seeking their input. We have incorporated their input into the announcement and we will continue to work with this office as things proceed. Thank you very much.

DR. SHEPARD: Thank you very much Matt. Are there, at this point, any questions from members of the committee concerning Dr. Kinnard's presentation?

DR. ERICKSON: Did I hear right, that this competition is only open to VA investigators?

DR. KINNARD: Yes, that is correct. The initial thrust is strictly within the VA. As you know, the VA for the most part only supports intramural research.

DR. SHEPARD: Yes. Dr. Murphy.

DR. MURPHY: What was the level of funding that will be provided entering this program?

DR. KINNARD: We have not attached a dollar figure to the level of funding for this program because we have no idea of the number or quality of the proposals which will be submitted. We feel that this is an important endeavor and once started will support various aspects of the epidemiology study.

DR. SHEPARD: Any other questions for Dr. Kinnard or Dr. Hobson?

A PARTICIPANT: I'd like a clarification, did I understand Dr. Hobson correctly that the current contractors are going to initiate a feasibility study to determine if they can get objective data on exposure?

DR. HOBSON: What is proposed is that, when clearance can be obtained for examination of all available records, an attempt will be made to design a separation, some mechanism of separating, at least on a probabilistic basis, those who were exposed to Agent Orange from those who were not. When it's been possible to design that, a feasibility study would be conducted. Whether it would be conducted by the UCLA group under Dr. Spivey or done by another group has not been determined. It probably won't be decided until the scope of the feasibility study is pretty well known.

A PARTICIPANT: But until that is completed, you don't intend to proceed with the epidemiological study?

DR. HOBSON: We cannot even complete the design of the overall epidemiological study until we know what we can do

in the way of separating the cohorts.

A PARTICIPANT: What about the morality and morbidity studies?

DR. SHEPARD: What about them? Well, are you going to be moving ahead with those now.

DR. HOBSON: Yes, yes, we shall, it's proposed that they will precede as soon as we get approval of the design and study as a whole. It's not intended that they wait for anything.

A PARTICIPANT: And they'll be done by VA?

DR. HOBSON: The VA has not done them in the past; generally they have been done by the Medical Follow-up Agency of the NAS-NRC. It's possible for other people to conduct them, but I doubt that the VA itself would do so. Although VA records constitute the basis for it, in the past we have not done that kind of thing ourselves and I don't think that

we would get into it in this instance. It's done by an outside body. Incidently, this will be very similar to the studies that have been done on prisoner-of-war mortality, by the Medical Follow-up Agency. They've been roundly praised as an almost ideal epidemiological study of their type.

DR. KEARNEY: Just as a matter of interest, in the Department of Agriculture we have been putting on computer all of the information related to cacodylic acid. We have a large number of keywords if that would be of use to you, we would be pleased to give you the accession number and the keywords to get into the computer.

DR. HOBSON: We'd very much appreciate that. For the benefit of those who do not know, Agent Blue is essentially cacodylic acid and that's what we're talking about now.

DR. SHEPARD: Any other questions from members of the committee? Thank you very much Dr. Hobson. As many of you know, the two efforts that were mandated by Public Law 96-151

were the conduct of the epidemiological study and an exhaustive critical analysis of the world's literature on phenoxy herbicides. As you also probably know, this latter effort has been ongoing under contract to JRB Associates, Inc., and we're pleased now to hear from Dr. James Striegel, who has been heading up that effort, to give us a report on the status.

DR. STRIEGEL: LITERATURE ANALYSIS REPORT I feel a bit dwarfed by the previous two announcements. We're at a different end of a curve of a cycle of production. We're now in the ninth and final month of a nine-month contract to collect the worldwide literature on all of the fourteen herbicides that were used in Vietnam, to compile an annotated bibliography of the science, the state of knowledge we have about the herbicides, and then to write a narrative report on our best scientific judgement of what this all means.

What this will constitute is something of a road map of the state of the science at this time, and hopefully it indicates what research is lacking and what needs to be done. We are on schedule, we are within budget. The annotated

bibliography is now approaching about four-hundred single-spaced pages. It is in final edit and being proofed now. A few hard-to-obtain articles are now being collected, annotated, and added to the bibliography.

The narrative report which will accompany the bibliography will be about a hundred and fifty to two hundred pages. It is now being compiled and reviewed by a number of scientists on our staff. Seven of twelve chapters have been drafted; tables, maps and charts are now in production. Literally as we sit here, there are people at our offices writing the remaining chapters. Next week, the report in draft form will be sent to a panel of consultant reviewers, including Dr. Walter Melvin at Colorado State University, who is a specialist in Environmental Medicine with several years of experience in herbicide Orange; Dr. Steven Safe at Guelph University in Ontario, who had a major role in the Canadian Government's recent study of 2,4-D and 2,4,5-T use in Canada; and Dr. Joseph Holson in California, who took part in one of the major reproductive effects studies conducted a few years ago.

We expect to deliver our final report to Dr. Shepard on schedule mid-September, which is about four weeks from now. It's kind of down to the stage where some people are getting a little white-eyed and gaunt and hands are beginning to shake as the deadline is approaching. We're working very hard to meet it and I think we will.

The only other thing that I would add to this point is that six months or so ago, when we first started out, we had developed an ideal outline of what we hoped to be able to talk about. That outline has been somewhat modified by, first and most important, the kind of literature we actually were able to identify. This is a literature search and review contract, and we have to talk about what we found as opposed to what we hoped would be there. Also, by comments from this panel, back six months ago, and by the concern to make this document a very usable research tool. It really should be a road map.

We currently envision a report that will be twelve chapters. Chapter 1 will provide a brief overview, and chapter 2 will

summarize the military use and applications of herbicides in Vietnam. I should point out that this outline that I'm going to run through very quickly is essentially all the same information we originally hoped to find and essentially in the same order, but has been broken up. Instead of in four large narrative chapters, it's several small chapters that address specific topics. I think that will help the scientific community and the public look for a specific issue and go to the bibliography and find the specific articles that address that issue. A more useable tool, when we get done. The third chapter, environmental fate and monitoring. The fourth chapter, metabolism. The fifth, on industrial accidents that have occurred. The sixth on acute toxicity. The seventh, on subacute and chronic toxicity. The eighth, on reproduction toxicity. The ninth, on mutagenicity. The tenth, on carcinogenicity. The eleventh will be conclusions and recommendations, the state of the knowledge and current gaps in that knowledge. And the twelfth will be an appendix, discussing current studies, protocols, things that we know are ongoing but are not yet at a stage that they can be reviewed in a final form.

To give you an example of how that works, chapter six on acute toxicity will begin with a section on mortality based on animal studies and would run through the herbicides of concern: 2,4,-D, 2,4,5-T, TCDD, Cacodylic Acid, Diquat, Picloram, Monuron, Diuron, etc. We'd have a section then following that on dermal lesions. The pulmonary lesions, hepathotoxicity, neurotoxicity, structural and functional effects on lymphatic tissues, renal effects, cardiovascular effects, a summary and conclusion. Then a list of references of all articles that we were able to identify revelant to these topics listed and numbered to refer to the bibliography, where an annotation of every article will be found, so that the tracking of our thought process can be seen.

Each of the chapter, each of the scientific chapters would also include a chart, a table of the references that we have found, organized by specific topics of interest. This would vary from chapter to chapter: for instance, the subacute toxicity might have a table for each herbicide that would

describe species, route of exposure, dose, frequency and duration of exposure, organ site affected, and the reference, the article where that can be backed up. You see, by this organization I think that we're really trying to develop a tool where the scientific community and the public can take this product and track through the issues of concern, the organ sites of interest, the effects of interest go to the literature immediately, and then to further studies of what needs to be clarified in the future.

DR. SHEPARD: Are there any questions of Dr. Striegel from the members of the committee?

DR. KEARNEY: One of the key issues I thought in the setting up of this contract was a sort of critical review of previous episodes, and there are many of these. How are we progressing on that?

DR. STRIEGEL: The industrial accidents?

DR. KEARNEY: Industrial accidents.

DR. STRIEGEL: We have collected what data there are on each of the industrial accidents and that constitutes a chapter, a separate chapter in the volume, for each of the industrial accidents. Let me flip back to that: for instance, the industrial accidents chapter is chapter five, it would have a table, a chart that would track the location of the accident, the year it occurred, the chemicals released, the duration of exposure, the organ systems effected--dermal, liver, whatever was reported--and then the reference articles that talked about that industrial accident, once again collated to the bibliography where a complete annotation occurs. The annotations are critical in nature, that is to say, what the article described and what shortcomings or judgements can be based on the data in the article.

DR. KEARNEY: Is there an attempt to critically evaluate the quality of the data from each of those episodes?

DR. STRIEGEL: Yes. That is the intent of the entire study.

DR. SHEPARD: That raises a very good point, Dr. Kearney, and one that needs to be reemphasized, I think. That this is not simply a bibliography, not simply an annotated bibliography, but is a critical appraisal by experts in the field of the data that have been presented in each of these reference citations. I think that that is really the unique strength of this effort. I think you can appreciate the extent and thoroughness which our good contractors have put into this effort. Are there any other questions?

DR. SHEPARD: INTERNATIONAL DIOXIN SYMPOSIUM I believe some of you are aware that we put together a conference on dioxin and plans are pretty well along. This conference will be held the last week in October here in Washington. I think that, in many ways, this will be a unique conference since it will bring together people with variety of expertise talking together and hopefully coming to some consensus on many aspects that deal with this complicated issue.

The individual who really has done most of the work in organizing, planning, leg work of all kinds is Dr. Richard Tucker, who is an officer of the Society of the Environmental Toxicology and Chemistry. He is here with us this morning to bring us up-to-date in terms of the plans. Dr. Tucker is prepared to answer any questions about the conference. Members of the committee have been provided a flier in their packet. This flier is just the initial request for registration. More information will be coming out. Dick...

DR. TUCKER: Thank you very much Dr. Shepard. I'm not sure I deserve all that credit, but I'll take it. I have brought other programs or other copies of the same program and they'll be available for anyone who wishes to take them is welcome to do so. They're located in the back there.

Just a few brief words on why the symposium, what we wish to accomplish and how we're going about accomplishing these goals. First of all, the conference is sponsored by the American Chemical Society, The Pesticide Division, The International Association of Environmental Analytical

Chemistry, The International Society of Toxicity and Environmental Chemistry and Enviro Control, which is the firm with which I am employed.

The purpose of the symposium workshop is really thought out, we think anyway, in a way where we hope to get a little more out of this thing than just a presentation of technical materials. We're hoping to reach conclusions; we're hoping to separate out those points which we can say with some assurity from those which we cannot. We don't want to spend a great deal of time in the symposium going over data which has already been gone over several times. Hopefully, we will present new information which will shed light on some of the problems which have been identified.

The way that we went about organizing the symposium in order to achieve these objectives was to put together a symposium in combination with a workshop. In dealing with the symposium, first, we're going to present overviews of seven technical areas. Now these overview, hopefully, will briefly

identify what information is available and what we can draw from that information. The session is headed up by Dr. Otto Hutzinger, who has been very active in other symposiums sponsored throughout the world dealing with dioxin.

Also what we're doing in the first day is to identify the problem for various perspectives and this section is headed up by Dr. Shepard. This session will include speakers from all over the world who also are facing problems with dioxin.

The second day--and I might mention, it is our four day symposium. The second day were going to dealing with Laboratory Safety and Waste Management. Again, we will focus on the technical speakers on new information that will probably be coming out shortly after the symposium in the scientific journals. This will be headed up by Dr. Alvin Young. In the afternoon on the second day we're going to talk about Animal Toxicology, which is headed up by Dr. Edward Smuckler, and Analytical Chemistry by Dr. Warren Crummett. Smuckler is at

the University of California, Crummett is with the Dow Chemical Company.

On Wednesday we're going to talk about Biochemistry and Metabolism. That's headed up by Dr. Steven Safe, and Human Observations which is headed up by Dr. Reggiani. Safe is with the University of Guelph, and Reggiani is with Hoffman-LaRoche. We're going to talk about Environmental Toxicology and Environmental Chemistry. The Chemistry is headed up by Dr. Phil Kearney; Toxicology, Dr. Eugene Kenaga.

Then the final day of the session, which is on a Thursday, we're devoted to two areas. One is on Risk Assessment. In Risk Assessment we're hoping to look at previous risk assessments that have been done on dioxin and to discuss them as well as the technology of risk assessment and how it applies to dioxin and other chemicals which create a problem.

Now in the afternoon we're going to present the results of the workshop and if I can go to that then, concurrent with the symposium, we're going to conduct a number of workshops.

There will be a workshop for each of the technical areas, again the technical areas are in Animal Toxicology, Laboratory Safety and Waste Management, Analytical Chemistry, Biochemistry and Metabolism, Environmental Chemistry, Human Observations and Environmental Chemistry, Human Observations and Environmental Toxicology. The workshops will be attended by speakers and also persons who do not present a paper but do have expertise and can contribute technically to these sessions. The panelists will address questions dealing in their particular technical areas. They will talk about what they can say, based upon the data and what they can't say based upon the lack of data or the conflict in the existing data. They'll talk about where they feel data are needed, what type of research should be conducted in order to get this type of data. Also they will identify the type of information which they feel should be in the analysis of risk or hazard of the chemical to both humans and to the environment.

There will be communication among these panels during the four days so that one group knows what the other groups

are doing and will help to input data in their deliberations. Thursday in the afternoon following the Risk Assessment session, the panelists, or the chair for each panel I should say, will present the results of their committee's deliberation. This will be followed by a discussion where all can comment on the activities during the symposium and workshop. That's about it.

DR. SHEPARD: Thank you Dick. Are there any questions for Dr. Tucker from members of the committee?

DR. GROSS: I have a short question, doctor. What do you envision is going to be discussed at the Risk Assessment session? What's your observation?

DR. TUCKER: On risk? Well, Risk Assessment is, the way I interpret it, is looking at the hazard to human health and environment from cradle to grave. From the environmental exposure aspects, from the hazard aspects.

DR. GROSS: In other words this would be sort of a compilation of everything that has been talked on together.

DR. TUCKER: Yes, and hopefully, what we'd like to look at is the risk assessment that have been done. We know that several have been done within the Environmental Protection Agency and also elsewhere within industry, and what we'd like to do is to have people who are in the risk assessment session to comment on these risk analysis as to their strength and to their witness if they have some.

DR. SHEPARD: If I may amplify on that. I think many of us are not familiar with the technology of risk assessment, how does one approach the whole process of assessing the risk to the environment or to human health or whatever. I think that many of us will learn how one goes about that. I think, I hope, it will be an educational experience dealing with that process because that is an emerging area which has gotten a lot of attention and I think it's important that members of the scientific community as well as others get a good feel for how one goes about assessing a risk.

DR. GROSS: If they are like any other risk assessment they probably will succeed in becoming confused.

DR. TUCKER: Well, that may well be. Hopefully, we can, as the process has evolved, we can at least address areas of consensus and areas of nonconsensus, and why there is such a nonconsensus.

DR. SHEPARD: Dr. Murphy.

DR. MURPHY: Two questions. Do you anticipate that there will be a more detailed program available in the very near future?

DR. TUCKER: Yes. There will.

DR. MURPHY: And secondly, what do you anticipate or do you have limited registration or what do you anticipate in terms of registration--in terms of registration fee?

DR. TUCKER: Well I--

DR. MURPHY: Looking at it even from the reduced rate per academia it's very healthy registration fee.

DR. TUCKER: Well, we're hoping to get around 250 to 300 people, we have made arrangements for 400 people. As far as the size of the registration fee, if you compared this with other ones, that is other symposiums that are occurring, I don't think that you'll find that this is high at all, in fact, it's low.

DR. SHEPARD: Any other questions, concerns, comments? Well, I certainly hope that members of the committee will be able to attend, and we encourage all members of the scientific community too. I want to stress that it's primarily a scientific symposium and will be conducted along scientific lines. I hope that it will produce some useful information. Of course, there will be a proceedings published so that the deliberation will be reflected in

those proceedings and made a matter of public record. We're happy that the literature analysis will be available at the time so I think that this will afford an opportunity for perhaps the review of that analysis while the ink is almost still wet. So we'll have an opportunity--at least, I hope, scientists who take the time to do that to review that analysis, and get some feedback. If there are no more questions we'll move on. Next we'd like to call on Dr. David Erickson to give us an update on the status of the CDC birth defect study.

DR. ERICKSON: CDC BIRTH DEFECT STUDY As most of you know CDC is in the process of conducting a case...

DR. SHEPARD: Could you speak up please. Maybe move the microphone towards you.

DR. ERICKSON: As many of you know CDC is in the process of conducting a case-control study trying to determine whether Vietnam veterans are at increased risk of having babies with birth defects. About a year ago we developed a

protocol. Since that time it has gone through an extensive review process although not as extensive as the VA has, apparently has, ahead of it for its epidemiological study. We received OMB approval for it. We're in the process now of beginning tracking efforts and plan to begin with the first interviews sometime in September or mid-October. I'm projecting now a completion date of somewhere around the summer of 1983.

DR. SHEPARD: Let me ask a question Dave and this is for clarification, some members in the audience may not be familiar with the term "case-control study," perhaps you could briefly describe how that's going to work and how the controls are going to be organized.

DR. ERICKSON: A typical epidemiological study is called a cohort study. It's typical in the sense that it attacks a problem forthrightly, it's not typical in the sense that it's most commmonly done in epidemiology. It attacks the problem, forthrightly, in the sense that it contains two groups of

individuals people who are exposed to a factor of concern for example, the case here, Agent Orange or dioxin. A group who are exposed to a substance and a group which has not been so exposed are contrasted through time looking for occurrence of disease and the contrast is made in the disease frequency among the exposed group and the disease frequency in the unexposed group.

In case-control study we begin with disease, if you will, and look backwards in time for the exposure. We start out with a group of babies who were born with and without birth defects, and we will be questioning the parents of these babies looking for the presence of antecedent exposure to being a Vietnam veteran so on and so forth. The reason for doing things this way is that it affords substantial economy and if you begin a study of birth defects with a group of men who were exposed and a group of men who were not, you'd have to look at many many thousand of them because the occurrence of birth defects is a relatively rare outcome. Because we begin with birth defects we have all the disease of this rare outcome gathered together and we can look for more frequent,

we believe a much more frequent occurrence that is exposure to being--the fact of being a veteran. I may have rambled a little too long.

DR. SHEPARD: I think that was a nice summary. Those of us who are not used to epidemiological terms, I think, have got a bit of struggle to get familiar with these terms, and I, myself, have now begun to get a little clarity on how some of these studies are conducted. I think it is important to note the basic difference between these two approaches, one starting with a group of individuals plus a control group and looking for what might happen to those groups and other starting with a disease and looking for the antecedent problems relating to that disease. Are there any questions from the members of the committee for Dr. Erickson? Yes, Dr. Kearney.

DR. KEARNEY: Dr. Erickson, you say that you will be through with the study in '83. Will you have a series of milestones?

DR. ERICKSON: I would say that unless we run into some substantial problems or it is determined that the study is impossible to do, unless we have some catastrophe there will be no interim report.

DR. KEARNEY: No interim reports?

DR. ERICKSON: No. The final report which we are expecting is based on the hope and confidence of success and will not be proceeded by an interim report. We do not have that in mind.

DR. SHEPARD: Dr. Bernstein.

DR. BERNSTEIN: May I ask, what is the target population?

DR. ERICKSON: The target population is a group of babies, parents of babies, who were born with what we call major congential malformations in the metropolitan Atlanta area over the last decade. We are focusing on metropolitan Atlanta because the Centers for the Disease Control has a

unique registry of babies born with congential malformation which is not available anywhere else in the country. What is unique about it is that it is virtually a complete count of all babies born with birth defects to women who were residents in a five county metropolitan Atlanta area and it's further unique in that we have a considerable amount of information about the families of each of these babies at the time of birth. This information will allow us, we hope, to find them at this point in time, but it is not an easy matter.

DR. SHEPARD: Dave, let me ask you what the status of identifying the controls is?

DR. ERICKSON: Well it's all done, we have identified controls through the state of Georgia by the vital records. Any babies born must be registered through the state. The state documents contain identifying information which will allow us to find the families of these babies. We have all the birth certificates in here, they are computerized, all of the names and addresses and everything.

DR. SHEPARD: And do I infer then that these are also in the same countries, the controls?

DR. ERICKSON: Yes, they are drawn from the same population that the babies born with birth defects are drawn from. That represents something like on the order of between 330,000 births and have a sample of those births as the normal ones has controls.

DR. SHEPARD: Dr. Murphy.

DR. MURPHY: I presume that you interview both parents and get the data not just associated with Vietnam service.

DR. ERICKSON: We will be questioning both mothers and fathers. The kinds of data which we will be gathering besides data which pertain to military service including occupational histories, reproductive histories, family, how many babies have you had, how many spontaneous abortions, so on and so forth, how many babies with congential malformation, and a history of major chronic disease in the

parents and siblings, and many of the things known or suspected to be factors in birth defects. And they are, therefore, things which we want to have on hand when analyzing the data. We want to know if there is a preponderance of other risk factors among the veterans or among non-veterans, we want to be able to take that into account. It also represents what we consider a major spin off of this effort in that we are going to be talking, we hope, to the parents of roughly 6 or 7,000 babies who were born with birth defects, and so this information gathered as a part of this study about occupational, major chronic diseases epilepsy, diabetes, it appears, will represent a valuable contribution to this science of etiology birth defects.

DR. MURPHY: Do you have a good method for sorting out social uses of chemicals in your questionnaire, alcohol and drugs of all sort?

DR. ERICKSON: Well, we will be asking parents about alcohol use. We will be asking about smoking. We will be asking about use of illicit drugs. It's anybody's guess as to what sort of veracity as to the answers to specific questions. We, what we did incidentially, looked into trying to obtain an exemption which will allow for us to assure these parents that we would keep all answers in absolute confidence, protect them from court orders and so on. We are unable to obtain legal rights, so we were knocked back a little bit in our effort to learn something about illicit drug use.

DR. SHEPARD: Yes, Dr. Gross.

DR. GROSS: Dr. Erickson, you clearly already know that you have basic data for so many deformed babies in the Atlanta this year. My question to you is, what sort of power do you see in this study, in other words, what kind of difference do you anticipate will have to been seen in order to be significant at all?

DR. ERICKSON: Well if defects are limited to a small group of veterans, and or to a specific and rare type of birth defects, it's unlikely that we will have any power at all. If the unexpected occurs and increase most of the malformations that we are concerned with, then we will have very good power to detect 20 percent, 15 to 20 percent.

DR. GROSS: It is a risk?

DR. ERICKSON: Yes, so then a nonspecific hypothesis, that is an increase among the majority of veterans, the majority of veterans for a wide variety of birth defects, we have excellent power and we can go down to near zero for depending on how specific you want to be at the hypothesis we are proposing. The number of controls we choose were based upon a the former idea, that it is a widespread increase in the risk. We will of course not only look at all birth defects together in 6 or 7,000 versus the several thousand controls that we will be looking at. Each specific type of defect if we can take any guidance from what happened in the field of teratology that is the production of malformations

by exposure by the fetus in uterol. We are speaking of something different here, we are talking of malformations caused by transmission through the male. If we can gain any guidance from what happens in exposure to the fetus specific chemicals cause specific pattern of malformation, and, so it therefore, important that we look at specific types of malformation, specific combinations.

DR. ERICKSON: I would say that it might be generous to say we know why 5 percent of birth defects occur. So whether they are caused by the male or female at this point and time, we don't know.

DR. SHEPARD: Thank you. Any other members of the committee have questions for Dr. Erickson?

DR. KEARNEY: Just one more, will you have an opportunity in your questionnaire to determine whether there has been exposure to other chemicals in a non-Vietnam mode--say in an agricultural mode? Would you be in an agricultural countries where you can get a reading, for example, as to the use of phenoxy herbicides?

DR. ERICKSON: Our data on our registry is based on metropolitan Atlanta. There are some rural areas, but, of course, very few people are from those parts of those five countries; I would say 95 plus percent of the babies in our study will be urban residents.

DR. KEARNEY: What are the five countries of people?

DR. ERICKSON: Well there is Clayton, Colb, Dekalb, Fulton and Gwinnett.

DR. GROSS: What what about the possibility of industrial exposure to let's say...

DR. ERICKSON: Well, as I said, we will be getting occupational history. As a part of that occupational history we will be asking: were you exposed to--I've forgotten exactly how the questions go, but there is something in there on what sort of a chemical exposure you might have had. I might say though that I'm not sure that Atlanta is a highly industrialized community. It is sort of a white collar and transportation town, and there is certainly not a lot of chemical manufacturing that I'm aware of in that area. So such exposure would have had to take place before these people entered the area.

DR. GROSS: Well, again following Dr. Kearney's question, if you go into occupation of the parents it seems to me that for someone who is a farmer, the proper question would be: what was the history of using phenoxy herbicide, just as much as whether the farmer was a veteran in Vietnam, and that would be--

DR. ERICKSON: Oh yes, sure I agree, but we are not going to have farmers, that's the point.

DR. KEARNEY: In many respects, that's the strength of your study, when you look at the population and you could probably eliminate that factor.

DR. ERICKSON: In fact, that is what I would say.

DR. KEARNEY: A mere example is a good situation.

DR. SHEPARD: I know it's in the protocol Dave, but it might be interesting to see, just to have a word on the method of matching in terms of numbers. In the Ranch Hand Study much was made of the fact the power, statistical powers, increased by, I think it was, 10 to 1 match, and I'm sure that Major Brown will have more the say about that. What is the matching potential I should say in terms of ratio?

DR. ERICKSON: Well in a typical epidemiological study, whether it's cohort study or case-control study, often the number of controls exceed the number of cases. Often it is equal, one to one. It may go up as high as four controls to one case, and this is done because you can increase the

precision of your comparisons by increasing the number of controls. The controls are increased because it is difficult to find cases, and it is cheaper to get controls in one way or another. In our situation we have an lot of cases, seven or eight thousand and in doing the statistical calculations required to figure out this power, that is the sensitivity of the study to detect certain effects, we found that we could get by with roughly 3,000 control babies, and that we added very little to the sensitivity of the study by adding more controls. The marginal gain was vitually non-existant for a considerable marginal cost. We set on the idea of obtaining 3,000 control families, which we will obtain, we can not know exactly how many case families we will obtain and that depends upon the participation ratio of cases. We can't get more cases. We can get more controls if somebody does not want to participate and we will eventually wind up with very close to 3,000 controls.

DR. SHEPARD: Thank you. I think it's important to point out that this very carefully constructed study, being conducted by the Centers For Disease Control in Atlanta, is

being supported in terms of resources by the Department of Defense, the Department of Health and Human Services, and the Veterans Administration. It is a joint effort, and we are all, of course, very concerned and interested in the outcome. I know that Dr. Erickson has personally put a lot of his time and energy into this study, and we commend him for his efforts.

Next I'd like to call Major Phillip Brown of the Air Force to bring us up to date on the status of the Ranch Hand Study another study, which we are all looking at with considerable interest.

MAJOR BROWN: RANCH HAND STUDY Thank you sir. The Ranch Hand Study is an epidemiological study of the Air Force personnel who flew the Ranch Hand herbicide orange missions in Vietnam in the years 1962 to 1970. The study potentially includes the total population of Operation Ranch Hand, approximately 1,200 personnel. All of these individuals are going to be asked to participate in the study.

The study will be in three phases. The first phase is the mortality study; the second phase is a physical examination or a cross sectional study; and the third phase is a follow-up

study which will go for a period of time up to 20 years. The first report will occur after the first round of questionnaires and physical examinations, and that brings us to pretty much where we are today.

The Air Force is in the process of obtaining proposals or bids from prospective contractors on the questionnaire at this time. The request for proposal was put forward on the 31st of July and the bids are due in toward the latter part of this month. Award of that contract will occur shortly thereafter depending on the number of bidders that submit bids, because we have to evaluate all bids.

The physical examination contract will be coming forward shortly, we anticipate putting that out for bids within the next several months. Questionnaires will begin immediately after the contract award, and hopefully all 1,200 Ranch Hands will decide to become participants in the study. The study also includes matched controls for all of the Ranch Hands. There are several sets of controls that I might mention. As Dr. Shepard had mentioned, we had to match controls for the

Ranch Hands that were in Vietnam. We wanted to match them with people who had similar experience. We had approximately 30,000 individuals who were available to serve as matched controls in two instances. One, is for the mortality study where we have a ratio of 1 to 5. That is for one exposed Ranch Hand there are five controls and in the morbidity study we have a 1 to 1 ratio with a control replacement scheme. There we have a 1 to 10 ratio, but at any given one point of time there will be only one control for the Ranch Hand in the morbidity study.

DR. SHEPARD: Are there any questions from any the members of the committee? Yes sir, Dr. Bernstein.

DR. BERNSTEIN: Will there be some evaluation of exposure? In other words, it seems to me that, for example, the pilots probably wouldn't or may not have exposure as compared to those who handle the materials and so forth.

MAJOR BROWN: That's a good question, but in fact the pilots do have exposure and the reason for this is that the

aircraft flew at a low speed with the cockpit windows open. This was because of enemy action ground fire they received. Venturi action carried the vapors, as well as mist often times up into the cockpit. This material could be sucked through the cockpit and out the windows of the aircraft. We have done some studies. In fact, Doctor Young was involved with this, where we did some simulation studies on the C123 aircraft using simulant. They are indeed exposed. The other thing that is fortuitous, I guess it's serendipity, is that in the early years of the war the concentration of dioxin in herbicide was higher than in the latter years. So we have a gauge, if you will, or not only the degree of exposure but the concentration of exposure.

DR. SHEPARD: Yes, Jon.

MR. FURST: Excuse me, have the members of the Ranch Hand or former members of the Ranch Hand all been contacted now or made aware?

MAJOR BROWN: No, they have not, Jon.

MR. FURST: Okay, that's important, and I will tell you why I asked. I came from Pittsburgh where I was yesterday, and I ran into a former Ranch Hand member. He is ill and very concerned about Agent Orange. He had a news article that led him to believe the Air Force was satisfied they had contacted everyone. He had not been contacted. I appreciate your clarifying this.

MAJOR BROWN: No, those letters which are going out to potential participants should be coming very shortly.

MR. FURST: Thank you.

MAJOR BROWN: Any other questions? Dr. Brick.

DR. BRICK: Well, how long do you speculate this study will take for completion?

MAJOR BROWN: Are you talking about reports, sir, or are your talking in terms of---

DR. BRICK: I'm talking in terms of final reports.

MAJOR BROWN: The various advisory committees that reviewed our protocol, which was quite extensive, had proposed that the study go up to as long as a period of 20 years. That recommendation was agreed upon and the study is indeed designed that way. In terms of a final "final report," it will be up to 20 years, but that is not going to impact what we learn fairly early. The only question that may answer will be the degree of latency for possible cancers, but if you have effects present today in those individuals you will know about that within a year or two.

DR. BRICK: You are talking about a ten year follow-up rather than a 20 year follow-up for the protocol proposes, is that correct?

MAJOR BROWN: It is, if you look at the point in time at which people were exposed. For example, some of those people were exposed in the 60's and we start today you get a 20 year follow-up, for some of those who were in the 70's you have a ten year follow-up, that's correct.

DR. BRICK: It seems to me, as a member of this committee, that it is very important that the Ranch Hand Study be completed as timely and as quickly as possible, because it is, I think, an important aspect of this committee's work. I think a ten year study will be helpful. I mean it is all right for a bunch of scientists to sit around and say well it's better to have a 20 year study. We are all aware of that, but I think that the immediacy of what we are trying to find out and what the veterans who are involved are trying to find out is: really, did Agent Orange cause trouble that was going to appear in ten years. Ten years is a pretty good length of time it seems to me.

MAJOR BROWN: Well, let me try to help you a little bit there sir. As I said before we are going to publish a report of the physical examinations and the questionnaires after the first round which should be within the next year or so. In terms of their concerns and their present physical status that will be available and we should be able to address those concerns.

DR. ERICKSON: The same as the mortality study I presume.

MAJOR BROWN: The mortality study will have periodic reports, that's correct sir.

MR. FURST: One more question. It has been raised by other people that there is something about those who are employed now as commercial pilots and whose very employment and profession depends on their good health, is there some mechanism by which we assured that they will be fully honest in their reponses to the questionnaire.

MAJOR BROWN: You're asking me the question but I'm not now the respondent, ah...

MR. FURST: I'm not saying that to put you in a bind, but it is a clear problem and you have to be able to explain to veterans why they should understand and believe in what the report provides. It's not a question of can the Air Force do it properly. It's a question of can we make sure that it is properly explained to the veterans so they will

have reason to believe it.

MAJOR BROWN: We in terms of trying to deal with that problem tried to lay out very factually and plainly for the individuals what the conditions of the participation in the study are. In addition, during the process of the questionnaire for example, Doctor Erickson had referred to in terms of sensitive questions, we included bias indicators within our study, just as he will I'm sure in his. Then this will allow you to evaluate whether or not those people are necessarily giving you the full truth. But in terms of their participation, this is a totally, totally voluntary study. If an individual does not want to participate there is no pressure to make him participate.

MR. FURST: Will there be confidentiality of their responses, I mean will people be able to determine if someone reports themselves as being ill in one way or another, that their employer will not be able to require that information about them?

MAJOR BROWN: The Air Force is going to, just as Dr. Erickson, have the same restraints upon it as he does: We

will protect that confidentiality but in the event of court order, we lose just like he does.

MR. FURST: Thank you very much.

DR. SHEPARD: Yes...

MR. LENHAM: Major Brown, are we to assume that when you come down to the physical examiniation procedures that they will be done in a central location?

MAJOR BROWN: Yes, that is correct. The successful bidder will have one central point for examination. Those people will be transferred to that point at government cost for physical examiniation.

DR. SHEPARD: Any other questions for Major Brown? Thank you very much Phil. We commend your efforts and again we are sure the committee and others share our interest and we want to stress again that this group of individuals probably represents the best documented cohort of individuals in terms of their exposure to Agent Orange.

That makes this study of particular value. For those of you who are still grappling with terms, this is a classic cohort study as opposed to a case control study. We are starting with a group of individuals and looking for diseases, Dr. Erickson explained a case control study. This is a cohort study, so we have a nice example of two different methodologies.

I would now like to ask the members of the committee who represent Service Organizations to briefly address us in terms of the organizations they represent, Dr. Brick.

DR. BRICK: REPORTS FROM VETERANS SERVICE ORGANIZATION

I am concerned continually by the adverse publicity that appears with reference to what the Veterans Administration is doing relative to Agent Orange. I wonder what, I'm asking this question of the chairman, as to what is being done by the VA to try to respond to some of this adverse publicity. For instance, a recent book very critical of the VA medical system called Wounded Men, Broken Promises. I am sure the VA is quite aware of this book. Let me quote about Agent Orange from a review I recently read, "The VA's response to the controversy about Agent Orange illustrates its indifference

to the health care needs of the veterans population." According to Klein, the author of the book, veterans exposed to Agent Orange, "are dying at twice the rate of death in actual combat and many of their children have been born with multiple birth defects." All this is put in an article and a national publication as if it's gospel.

"Yet the VA has consistently denied any relationships between the 44 million pounds of dioxin to which the soliders were exposed and their deteriorating health despite all the information gathered by Agent Orange Victims International. The VA has not only ignored the complaint but has even ordered one employee of it's Chicago Regional Office to stop assembling the material and to guarantee that her duties were changed to restrict her contact with veterans."

Quite obviously this is not very factual, it seems to me, we come to these meetings and we listen to the vast amount of work and also the vast amount of paper that has accumulated in these meetings with reference to what the VA is trying to do to come to grips with this problem. Yet this publicity

pervades the media, TV, radio, publications such as this. Even yesterday in the New York Times, August 18, one of the new members of this committee criticized the study that Dr. Spivey is heading with reference to his bias relative to the problem, because he was quoted as saying, "There is little data, there is to date little evidence of any specific human health defects." Yet we come to this meeting, all of us here and we listen to the scientists who know a lot more about this than most of us do, trying to indeed pose a study that is unbiased and trying to get scientific information of what this exposure in Vietnam has done to the veterans exposed.

It seems to me that this type of criticism is non-factual. Most of it keeps escalating despite the efforts of the Veterans Administration to try to create a study that everyone can accept, and I bring up the question again as

to what extent this is going to be possible, with all this criticism that we keep reading about and hearing about. I have more and more doubts as to whether anything that comes out of such studies is going to be accepted by the people mainly concerned.

Now, looking at the other side of the question, what does the VA really do with reference to these individuals who claim various diseases, various conditions ranging anywhere from nervous conditions to cancer and this becomes increasingly evident in some of the cases I personally handled before the Board of Veterans Appeals. I think the VA has done a creditable job but I don't think the VA gets credit for doing a creditable job. For instance, in all of these cases now, for compensation purposes, VA concedes, exposure to dioxin if a veteran has served in Vietnam. I think that's a very creditable and an honest statement of what the VA is trying to do. I think the VA has given reasonable doubt with reference to this question of exposure relative to veterans. We handle a lot of claims in the American Legion and I see a lot of these claims. We don't have the data base, which this committee is trying to collect, which these studies are

trying to address, with reference to whether a patient who is 39 years old or 40 years old, as I handled one recently before the Board of Veterans Appeal, with cancer of the pancreas, who had served in Vietnam--whether his exposure to dioxin had anything to do with the fact that he had a cancer of the pancreas at this early age. This particular case was sent to the Armed Forces Institute of Pathology by the Board of Veterans Appeals which leans over backward. Every case is as I find it, an attempt to give the resolution of reasonable doubt in favor of the veteran, and we get a report back from the AFIP which is quite factual. They point out that patients who have not been exposed to dioxin, have never been near Vietnam, also have a rate of incidence of pancreatic cancer that is that is not completely rare. They bring up statistics and data on factual evidence so that we go round and round on this problem and hopefully we will get some answers. This is the reason I am a little leery about the time that it is going to take to get this Ranch Hand Study done. I think the Ranch Hand Study is a very very important study, and we have been reassured by Major Brown, there will be some data within two years. I take it that will tell us something about this particular cohort that was exposed.

DR. SHEPARD: I wish I had the answer to your question. How do we deal with the adverse publicity? I suppose there may be two broad approaches that one might consider, but I'm certainly no authority on how to deal with the publicity. One would be to develop a strong methodology of process, if you will, for addressing each and every adverse comment that appears in the media. That would be at least a very time consuming process, and I'm not sure we'd win the battle. I think that would cast the VA in a very defensive posture. I personally feel that a meeting such as this open meeting, instances where members of the VA staff, myself included, and other members of my staff appear in public forums, such as congressional hearings and legislative efforts on the part of states, are beneficial. As you well know, I recently testified before the California State Assembly Hearings relating to their proposed legislation.

I think that the record will show that contrary to some allegations, the Veterans Administration has, in fact, been very open, I hope, forthright and honest in it's dealing with every issue. I personally have no evidence to suggest that there has been any kind of a cover-up or hiding of

information. I guess that one can hope with the passage of time the VA will establish a creditable reputation that will speak for itself rather than responding to each and every allegation. We have, on occasion, perceived that something is being said that is, in our view, out of line and we have addressed those comments. But I don't think we do it in every case and I'm not sure that we should do it in every case. But I certainly would like the comments from the rest of the committee. Maybe we should look to the committee to advise us on how we should deal with this issue because it is very much an important part of the whole problem. I would be very happy to receive any suggestions and comments. I think also the Administrator in his recorded message to you suggested that one of the missions of this committee is to spread the word on what the VA is doing in order to strengthen out that record. But please any members of the committee who would like to respond to Dr. Brick's comments I would appreciate it.

MR. FURST: Dr. Brick, I believe my statement and answer would explain my own remarks. May I?

DR. SHEPARD: Sure.

MR. FURST: So that the committee understands the position that the Task Force is in, we filed for a temporary restraining order on the basis of the fact that most veterans, and I shouldn't say most veterans, many veterans at this point in time refuse to go to the Veterans Administration facilities. Most of them have their own reasons and I can never propose to speak for them all. I know that there have been problems many times. We have veterans returning from combat wounded who return to Veterans Administration hospitals that have evolved over many years, into facilities that would best care for World War II and Korean war--older veterans. We are not prepared for the influx of people requiring acute care, people returning recently wounded. Some of those veterans found the caring in Veterans Administration hospitals such that they were willing to make the commitment that they would never return. I don't wish to judge whether or not that is an appropriate judgement on their part, but so many of the veterans that we deal with feel that the Veterans Administration has demonstrated bias with regards to it's willingness to take a look at Agent Orange. What we have requested in conversations with the Veterans Administration on Agent Orange is that they understand

when we contested the ability of them to do an unbiased study what we were most concerned with was not the fact that we questioned whether or not they were able to do the study properly or scientifically, but that the study had been ordered to answer the concerns of a great many Vietnam veterans who were in very real states of fear and legitimate concern about the likelihood of their own health being damaged and that the study, be it properly done or not, would be of little value if actions were not taken to make that study believable. In other words, what good does it do to answer someones questions if you've done nothing to make sure that they believe your answer. What we did was file for a temporary restraining order, we only asked them to hold up for several days and we lost, the court was unwilling to provide that to us. We then found ourselves in a position almost a year later when the Veterans Administration did award the contract, finding press releases that said thay our request for a temporary restraining order, which had been denied, was in fact the cause for the full year's delay. I believe you clarified that in Congressional testimony.
I had been so informed and I can't at this point

document it, that has been the word of mouth. What I would propose to you is that the Veterans Administration has hired Dr. Spivey to do a study and to do it I would hope in such a way that...

DR. SHEPARD: Excuse me Jon. I have to stop and correct you, this is to design a study.

MR. FURST: To design a study, I beg your pardon.

DR. SHEPARD: There's a difference.

MR. FURST: To design a study that will in an unbiased way determine to what degree their health is at risk and to what degree we can consider Agent Orange a hazard to their future. Regarding Dr. Spivey's remarks before the California State Legislature: We found it unusual that a man designing an unbiased study would make recommendations at this point to any legislative body. His statements do not reflect the impressions presently heavily understood among Vietnam veterans. He has said, for instance, that fear generated by the current publicity is very likely to be the most serious

consequences of the use of Agent Orange. He is designing a study which is supposed to find out what is the most serious consequence of exposure to Agent Orange. Dr. Spivey has placed us in a circumstance where we simply can not support him because he has made such a statement. We cannot represent his work as clearly unbiased because he is going on the public record as saying what he has said. We have no question about whether or not he's capable of doing it properly but he has impeded the likelihood of veterans believing in him and therefore, we felt we had no choice but to criticize him and ask that he be replaced with someone who is unquestionably unbiased. I thank you for the opportunity to respond.

DR. BRICK: I respect your remarks Mr. Furst.

MR. FURST: Thank you.

DR. SHEPARD: Does anybody from the committee have anything to say in response to Mr. Furst? I have a few comments of my own but I would open the floor up to the members of the committee to respond to his comment. Yes, Dr. Hodder.

DR. HODDER: Well one point, just a comment on Dr. Spivey, I haven't seen the rest of the testimony but the statement that fear that may have already been generated by the question may in it's own right have been harmful. I think that he is stating that the impact of the fear has been well documented, and I don't think that he's evaded the question of whether he may also find another issue. Second, if the scientific investigation is done correctly, the investigator's personal feelings do not enter into it. This is one of those things that design or method can do to avoid personal preferences from affecting the results. So many times investigators will come up with scientific research the results of which are contrary to what they personally feel. The question then becomes one of their integrity rather than their scientific capabilities. I think you'd have to keep those two separate. If you were to say he's not capable of doing the study because his personal opinions may differ from the results of the study, that's a question of his integrity rather than his scientific capabilities.

MR. FURST: I can provide you with a copy of the assessment here.

DR. SHEPARD: Yes, Dr. Gross.

DR. GROSS: I would go on...

DR. SHEPARD: Could you sit up at the table and use the microphone because we are being recorded?

DR. GROSS: Yes, I would like to discuss some of the distinctions that Dr. Shepard made earlier, that is the difference between designing and conducting a study. I would concede that someone who selects the subjects for investigation, if in fact he was biased, could either consciously or unconsciously undermine the study because of that. But I can't see how designing a study which all of us are reviewing here, on the basis of our judgement, to determine whether the design is a good one, a poor one or how it can be improved even with an alleged bias on the part of Dr. Spivey can have that result. The design speaks for itself.

MR. FURST: I am not saying that Dr. Spivey is not a man of high character, only that Dr. Spivey has said things that make our clients population extremely dubious in their willingness to have confidence in him, the man who will design what questions the study will answer.

DR. GROSS: Will you agree, however, that whether the design that he is putting forward, whether that design is a good one or not, is an issue highly dependent on someone's personal views.

MR. FURST: Oh yes I do. But again we have to ask the question, why do the study, even if you do it well, if the population who has asked for the study will disbelieve it. It does no one any good to have a wonderful study if there are reasons, readily in place, before them to question it's veracity. I don't think it's what Dr. Spivey has done, it's that he has put us in a position where we cannot avoid referring to his remarks. We cannot avoid asking people to understand that is clearly seen as bias by the veterans who

are asking the study to be viable. We must address that question, I understand what you are saying and I understand that the design of the study will be referred to other scientists for it's validity.

DR. SHEPARD: Dr. Erickson.

DR. ERICKSON: To follow up on the review where other scientists follow up on the issue of review of this study design, it seems to me that it is very important that people like yourselves and other veterans organizations get very actively involved in this review so that, whatever milk that has been spilled here, at least the study which is conducted is a result of a consensus not only of scientists but of the veterans who are the subject of this study.

DR. SHEPARD: Dr. Brick.

DR. BRICK: I'm speaking to you, Jon, I'm more at ease with this particular study now that Dr. Shepard has told us

who is going to review this study, not only this committee. I am sure that some of the members of this committee are quite capable alone of reviewing this in a very critical fashion but Dr. Shepard told us at the beginning of this meeting that the Office of Technology Assessment, the interagency Agent Orange Working Group and the NAS-NRC are going to review this study in a very critical manner. I am sure and I feel that we can now be guaranteed that the protocol will turn out to be acceptable to all of us despite this...which you have highlighted. I'm quite content with the nature of the study that is going to come out of the protocol.

MR. FURST: If I may say one other thing to address his other point. Dr. Brick, you mentioned in the national press you had seen that Vietnam veterans are dying at a faster rate and having more birth defects. I wanted to clarify for the panel's sake that the National Veterans Task Force on Agent Orange, as a cohort group, tells veterans very clearly that the suspicion of increased cancer death and increased likelihood of birth defects in offspring is a result of

concern by street counselors and people who have the veterans' best interest in heart. They are seeing an increase, not so much in the incidence of cancer, but in the kinds of cancer which will normally not be seen until later ages. This is an impression that I get from the people that I talk to. And the other question is the birth defects that they are now seeing, granted being reported by self-selected individuals, but those birth defects are also seen in the animals literature on dioxin exposure. And so their concern about birth defects and cancer are understandable. It's that those things have not been studied so that we can clearly know whether veterans are more at risk of cancer and birth defects. There is good reason to find out that we must answer those questions now. I cannot speak for those people who said that in the article but I wanted to clarify for you what our position is with other veterans.

DR. SHEPARD: Thank you, Jon. Dr. Murphy.

DR. MURPHY: I wonder if I could ask Jon the observations of the Task Force on the parent's increased incidence to these problems that you referred to. Has the Task Force ever engaged anyone to examine the specific cases?

MR. FURST: We have not been able to afford hiring scientists to do so. We have a scientific advisory panel which looked at the information, and the scientific advisory panel finds it very interesting. When the press reported the Agent Orange story in my particular area, self-selected individuals seeing the news stories reported to us and asked for information. We insisted that we would not inform them whatsoever of what kind of symptoms or what kinds of dangers were proposed as dangers from exposure to Agent Orange until they would explain to us and document to the best of their ability what kind of health history they have had, have they had serious health problems, and of what kind. That is certainly not scientific, but I believe that it adds to the likelihood that we'll have a better idea of what it is,

their complaints amount to. We find some degree of a likeness, 89 percent of the people that we talk to, and this is not scientific, but 89 percent of the people who self-selected themselves and came to us to ask for information, reported skin rashes, etc. I can understand that concern because the media carried information that skin rashes would result.

That is the kind of process that we have seen generate questions among the counselors. Counselors very often raise the question of why are so many of the people who report that they have cancer, that the doctors tell us isn't usually seen in older people and why are we seeing birth defects of the hands, fingers, feet and toes. The laymen reading literature would find terrible suspicious evidence. So what we are proposing is that people understand that there are a lot of questions to ask and that it is a brutal way to find out what science will be able to clarify for us. Does that address your questions?

DR. MURPHY: Well, yes, I guess it does. It just strikes me that if you can identify the problem, the street counselors undoubtedly have thought about this, sorted this out, if not in a professional way, but identify in an intelligent way what you are seeing, you ought to be able to convince somebody that...local epidemiologists, for example, to sort of just pick up on this from pure academic interests. This is my question, have we been able to approach anybody from that standpoint not going into a big full blown study getting this kind of advice?

MR. FURST: Having them look at it.

DR. MURPHY: Yes.

MR. FURST: Yes, we had them to look at it. They have not clearly identified for us what it is they see except that they find it unusual--the pattern of health problems.

DR. SHEPARD: Excuse me, Dr. Lingeman.

DR. LINGEMAN: I can tell your about a source for consultation about cancer which would cost you or your organization or your clients nothing. They can get a free consultation about whether the type of cancer that they had is unusual in that age group. This source is the AFIP and its special Pathology Registry. Use of this Pathology Registry requires that the surgeon doing the biopsy informs the pathologist in the hospital where the biopsy is done to send the tumor to the AFIP. If anyone is disenchanted with the Veterans Administration, they could consult a private physician. We have to document that a cancer does exist. We are, of course, interested in knowing whether it is an unusual form of cancer that is not seen often in young people--an old man's cancer occurring in a younger person for example. These AFIP consultations are absolutely free of charge. The report is sent to the referring pathologists. Now the AFIP has the capability, which we utilized recently in the case of a man in his thirties who had a cancer that we thought this was unusual for this age. We asked the computer at the AFIP to give us a writeout on all cases of this cancer which had occurred at the AFIP since they've been keeping records. We found that 5 percent of all

of cancers at this site did occur in men in their thirties, although it seems unusual when you happen to see only one of them. But it requires a couple hundred cases to produce a bell-shaped age curve to show that five percent can occur in young people. There is a similar situation with other forms of cancer. We can use the AFIP data file to tell us what cancers do occur in men in their thirties. If you will help us get this material into the AFIP Registry, we can answer the questions that much faster.

MR. FURST: I would like to tackle what Dr. Lingeman said because in action and I am sure the service organization representatives here will concede that if you have a specific case with reference to a veteran who has an unusual type of lesion, whether it be cancer or some disseminated vascular disease, etc. etc., this can be obtained in the AFIP and the Board of Veterans Appeals. I must say I commend the Board of Veterans Appeals. If you bring this up, as I do repeatedly with reference to cancer, particularly in young veterans who have served in Vietnam, invariably we see the presentation

of someone in the field or the veteran himself or his representative that mentions that he was in Vietnam. I wonder how many people in this audience and in the general public understand and realize that the VA concedes exposure due to dioxin if the veteran had served in Vietnam. I don't think that that's been widely publicized. I'm not sure that it's true Dr. Brick, in the rating book in the Board of Veterans Appeals, a decision that I have seen time and time again, exposure is conceded and then the question comes down as to whether the exposure has anything to do with the condition the veteran had. Is this correct?

MR. MULLEN: Well the Veterans Administration Program Guide 21-1 Section 0-18 concedes exposure to herbicides, the problem is that this is a guideline and it's not generally made publicly available. This is for the part in the adjudication section so I don't think it's been widely publicized at all, and I do question its effectiveness if as you say it actually reads that they will concede exposure to dioxin. Then what does that do except to allow for service connection only for chloracne.

DR. BRICK: But at the present time with the state-of-the-art with reference of the knowledge that this committee is trying to expand or trying to scientifically establish, you are absolutely correct. I think there are some tumors, tissue sarcoma, this is one of the tumors that been related to dioxin exposure, a very rare type of tumor. I have personally not seen in handling hundreds of cases before the Board of Veterans Appeals, but the state-of-the-art of the knowledge as such that I agree with you that the fact that the VA concedes exposure to any veterans who has served in Vietnam doesn't basically mean a heck of alot. That's what you are saying, and I...

MR. MULLEN: Unless he has chlorance.

DR. BRICK: Right.

MR. MULLEN: One other thing that I want to point out to you, I work at the Board of Veterans Appeals and have been

there for about five years. The figures that I got from DVB on August 3, of 566 cases that had been allowed out of 9,550 claims, none of the has been allowed where the condition has been attributed to dioxin or herbicide exposure, they were all allowed for other reasons. Either they occurred within a certain period or they were secondary or they were aggravated or incurred. Now of all those, 527 were for skin conditions, that's about 93 percent. I believe that the guidelines that DVB has right now are totally ineffective. Now the guidelines as I understand them, read herbicides, yet they only adjudicate, in cases as far as Agent Orange exposure and I think it's very limited, I think I brought this up once before in our committee and I don't see where there is enough interaction between DVB and DMS at this point.

DR. BRICK: Well, my own feeling on that is that, as scientific members of this committee will point out, that it is the purpose of the committee and the various other task forces with reference to trying to find out what the long

term health effect with reference to these exposures. Again I've come back to the Ranch Hand Study which, I think, is going to be an important landmark with reference to solving the problem.

DR. SHEPARD: I think what Mr. Mullen is raising a question about other herbicides that were used in Vietnam, and certainly the literature analysis will address all the herbicides used in Vietnam so at least we'll start with a critical analysis of what is now known about health effects of other herbicides other than phenoxy herbicides. From that we can move into looking at other problems affecting our veterans. But I'd like to clarify one point, it's complicated, and it's a difficult one to explain, but my understanding of the claims adjudication process is that an etiologic factor does not have to be established. Whether it's due to phenoxy herbicides or whether it's due to Agent Blue or Agent Pink, or Green or whatever, is really in a sense beside the point if an individual can demonstrate that he has a condition which was either incurred or aggravated during a period of

duty regardless of the etiology, but that is the basis on which these adjucations are decided. Now, you mentioned one point that out of some 9,000 claims that were filed by veterans motivated by a concerned and that these might be conditions arising from exposure to herbicides. That does not represent the total number of claims obviously that has been filed by Vietnam veterans. In fact, it is a very small percent and it also is true that some 500 claims have now been adjudicated in favor of the veteran. There is some suggestion there when we talk about giving the veterans the benefit of the doubt, there was just enough doubt in the minds of the adjudicator that there might have been due to exposure to herbicides that those were adjudicated in favor of the veteran. Now, it's little different to say that a claim was service-connected on the basis of a doubt that is in adjudicating in the favor of the veteran. That does not equate to saying that was the cause of the illness, and I just want to make that very plain because I'm afraid that some people have the impression because the VA has service-

connected disabilities. That is a tacit recognition by the VA that these were in fact due to herbicides and you know that's not the case. I just want to set the record straight.

MR. MULLEN: Yes, I think I said that not one has been allowed due solely to herbicides exposure, they were all allowed for other reasons.

DR. SHEPARD: Well, yes that's true; they were allowed. There are a number of claims in which there is this potential, in the mind of the adjudicator, and mind you these claims are adjudicated by a wide variety of people. They don't all come into this committee, obviously they don't all come to my office. I'm not a part of the claims process, so the claim was service-connected under the presumption of the possibility that might have been due to the exposure to herbicides. Let's see did you have anything else you wanted to speak of, Fred?

MR. MULLEN: No, not at this time.

DR. SHEPARD: Bob.

MR. LENHAM: Obviously from the comments that we have just heard, we are still continuing to deal with a very frustrating problem as VA Administrator Nimmo related to us this morning in his comments. It is very frustrating, it's particularly frustrating from an organizational standpoint when there are articles and news coverage throughout the land that produces a lot of fears in a lot of individuals. Whether it is the family member or the veteran himself and it's their fear that I think all of us here today, in one way or the other, want to have dealt with. Again, as the Administrator stated he's joining us on this bandwagon. It is a frustrating problem. He has indicated that he does wish that we could provide some conclusive type of a statement, in the answer in the response to questions that the veterans posed to us. We also concur with that. The fact remains though that all of us here today and all of us who are concerned with this issue is still relying on the scientific research

that is ongoing. It is also apparent that this research is not going to really be able to provide us with any tools that we need, specifically, for maybe another two years. That's just something that we are going to have to deal with and have to look at it objectively and try to handle it as best we can. I certainly want to wish Dr. Erickson a lot of success with the study that he is undertaking because I think from all the questions that we get in our organization, one of the most common is the birth defect question and concern. You feel for these individuals out there. Many of them are so concerned that they do not want to start a family, and myself or Dr. Brick or anybody else cannot tell them what to do. All we can say is we have at hand right now and try to state it just as objectively as we can, and let them make their own difficult decision. I seem to repeat myself, I think that at every meeting that we have, because we are basically, from an organizational state, we are at a standstill right now. Not that nothing is being done, but we have not gotten anything conclusive to do anything with.

DR. SHEPARD: Okay, thank you Bob. Fred, do you have anything else you want to say?

MR. MULLEN: Yes sir, I'm very encouraged by the fact that the VA research and development team will be working on Agent Blue, and I only have one question. Dr. Kearney, you indicated that you would punch in cacodylic acid information into a computer. My question is, is the cacodylic acid information that you will be putting in there, will that correlate with the missions that used cacodylic acid and particularly Agent Blue, and I might ask the same question of Dr. Kinnard?

DR. KEARNEY: Yes, the material we're putting into the computer with all the key words is all the literature we are aware of, dealing with, chemical and environmental medical literature which has occurred in the past. We're going to have to take on faith that you can link the two that we're doing that here is a number of other situations. We're going to make that available to you whether you can bridge the gap

of that information remains to be seen, alright?

MR. MULLEN: Are you aware of whether in the United States...it's been mentioned before that the foresters in upper north and northwest use cacodylic acid. In fact, I think, there's a newspaper article, we're using it here right in D.C. to combat Dutch Elm disease. Well my question is, is that just cacodylic acid or is that cacodylic acid with an additional arsenic component?

DR. KEARNEY: I believe the practice we use is something called a poison ax, and this is to rouge out certain trees in the forest and to my knowledge that is cacodylic acid.

MR. MULLEN: There is no additional arsenic added that you know?

MR. KEARNEY: Well, right now you're pressing me, I'll have to do some homework on that.

MR. MULLEN: OK, what I'm getting at is, the Agent Blue that was used in Vietnam was 3.1 pounds of cacodylic acid

plus 1.7 pounds of arsenic per gallon. Now, my question is, is that the same mixture we're using here in the United States or is your study on cacodylic acid going to be exclusive of, Dr. Kinnard, is it going to be exclusive of the additional 1.7 pounds of arsenic?

DR. KINNARD: Again that's a question I'm not in position to answer. I can say I spoke with Dr. Kearney during the break and he indicated to me that there's some information that would be helpful as we proceed with the solicitation and the review of the proposal which I think will be very helpful for our investigators but can't answer that question now. Dr. Hobson has a...

DR. HOBSON: Barclay?

DR. SHEPARD: Yes.

DR. HOBSON: I believe that you're misinterpreting the composition of Agent Blue, but I'd like to refer the question

if I may, to Al Young who is fully conversant with the exact composition of Agent Blue, I'm sure. I think the arsenic that you're quoting is the total content of arsenic which is included in the cacodylic acid not as a separate component but that's the arsenic in the cacodylic acid.

MAJOR YOUNG: Right, that's the calculation you're giving. Blue is 3.1 pounds of active ingredient cacodylic acid and sodium cacodylate with the mixture, 15 percent is arsenic. The molecular weight of cacodylic acid includes 74 percent arsenic: therefore 1.7 pounds is expressing the amount of arsenic component; but it is still the organic pentavalent arsenic.

MR. MULLEN: I want to question the 1978 OEHL report. You indicated there were trace quantities of inorganic arsenic in the Agent Blue spray. What constitutes a trace quantity?

MAJOR YOUNG: At the time we were not able to determine what the particular form of arsenic was. We have since

completed that analytical work and indeed what we thought would be a very small percentage is what we found. You're talking about .02 percent of arsenic trioxide and, of course, this is very concerning to us from the point of view that many of the toxicological studies have been done with cacodylic acid having a 90 percent purity. Can the inorganic arsenic from that formulation be responsible for the adverse effects rather than the organic arsenic. Thus the Blue appears to be less contaminated, from the data that we have now, compared to the commercial formulation of Phytar 560. The military formulation was labeled Phytar 560G. One was 2.7 pounds active ingredient versus 3.1 pound active ingredient. When we compared them we found the Blue contained far less inorganic arsenic than the other commercial formulation.

MR. MULLEN: OK, thank you very much. I only have one other thing. Dr. Lingeman was speaking earlier about the AFIP. Now I haven't heard anything in the last couple of

meetings regarding the tissue registry. I did get some figures from DVB regarding claims back in Janaury and I also read, Dr. Irey's sample report. There seemed to be a discrepancy in figures. I believe there were approximately 180 samples in the registry from what I saw of his report, this was in seminal fluid, etc.,etc...and 137 came from VA source. The rest were from outside sources, civilian doctors, hospitals, but the number of skin conditions and cancers seen in the DVB claims figures far outnumbered the number of tissue samples. I was wondering could this possibly be through a lack of SOP at the VA adjudicative offices or at the hospital itself. We know, for a fact, a lot of the physicians that practice in VA hospitals are there for training purposes and they may not be as well versed in handling of tissue samples because of a lack of time and lack of written guidelines on how to have this material forwarded to the AFIP for inclusion in the tissue bank.

DR. SHEPARD: OK, I'll ask Dr. Lingeman to explain that...but I think that one can say in general a very small

percentage of skin condition diagnosis are established by tissue biopsy, most diagnosis of skin tissue, skin condition are made simply on the basis of a visual examination and palpation so that one would not expect the AFIP figure to match the DVB figure. Dr. Lingeman do you care to elaborate on that?

DR. LINGEMAN: I think the publicity about skin lesions has caused an excessive attention to the skin perhaps. Also because you can see skin lesions, the AFIP registry has received a large number of such lesions, of which none, I've looked at all of them and none of them, that we've seen so far have any characteristics of chloracne. However, some had been acne. There is a separate registry where we send every skin biopsy. However, that you cannot distinguish chloracne from other forms of acne from a biopsy, therefore, we need more documenting history than we receive--mainly, the duration of a lesion, and whether or not it was present prior to service in Vietnam, and whether the lesion occurred during service in Vietnam because these usually appear within weeks

after exposure. It should be possible for this to be established if a person entered the Armed Forces and has a photograph of his face prior to service, and a beautiful clear complexion, while the veteran was in service he develops this acne form lesion. It would be difficult to establish I'm sure. I think that anyone that would require this kind of documentation to establish the cause-effect relationship of anything. Acne is to common a disease in men in this age group to start with and they are very susceptible to ordinary acne. There are fairly specific lesions of the skin caused by arsenicals, and it's been well documented over a long period of time. Usually people using medication containing inorganic arsenic now here we are talking about an organic form which can break down I guess into...an inorganic form?

DR. SHEPARD: Yes.

DR. LINGEMAN: We're aware of the arsenicals which were used, we know what to look for, and we have yet to see one. Most of the lesions we have seen have been such things as a nonspecific rash which could be anything from a mosquito bite

to a reaction to a medicine. Frequently, we write back and say are you taking any medication, has there been an insect bite or other cause for this. But we're looking for specifically acne, we're looking specifically for arsenical lesions. These are the only two that we know are specific.

DR. SHEPARD: Thank you, Dr. Lingeman. I think we better move on. We would like to acknowledge the presence of a number of representatives from state organizations. I would first like to call on Dr. Robert Bernstein, Commissioner of Health, State Department of Health in Texas. Dr. Bernstein it is a pleasure to have you with us, sir.

DR. BERNSTEIN: STATE ACTIVITIES - TEXAS. Thank you very much, Dr. Shepard, I don't really have many comments. I'd just like to say that the Texas delegation is very pleased to be here. I'll just tell you what happened in Texas during the last regular session of the legislature. A bill was passed without, as far as I know, any opposition, sponsored by Representative Larry Don Shaw, who's sitting in the second row. He just came in. It is a means of assisting Texas veterans in the matter of Agent Orange. It calls on the health department, which I head, as the principal

head, as the principal agency; it calls upon the University of Texas system to assist; it calls upon the Attorney General to assist where appropriate to get records and so on. We have with us today a number of other officials besides Representative Shaw. We have an M.D. Anderson Hospital representative, Dr. John Newell; and Dr. Murphy, of course, sitting on your panel here, is from the University system. Plus Dr. George Anderson of my office, Dr. Forrester who belongs to the Veterans Hospital in San Antonio and also with the University down there, and I don't know who else is here. Oh, I'm sorry, Dr. Neaves of the Health Science Center in Dallas. We came really to see the state-of-the-art and see where the Veterans Administration has been and is going so that we won't try to plow ground already plowed, and also to work with the Veterans Administration, too, in carrying out our mandated program. The fiscal year doesn't start until the first of October. We expect very shortly, to develop our own program and it, as I say, will be adjunctive hopefully. We have been working with our own veterans organizations who I must say are very will ready, very knowledgeable as you know, very articulate, and quite vocal although perhaps not

like in other parts of the country. But we listen to them, and I think that if we can impress them in some way, they will develop credibility because clearly the veteran and outside forums like this just don't have the credibility in the military system and less in the veterans system. I don't know what that's all about precisely, except I know at the hospital level there is a great problem with communications, a tremendous problem, and whether your people don't get the word, or I think it's more perhaps they don't get the word across that they already know, that is your status. Seems to me that is a great part of the problem. Irv Brick here, who is an old, old friend, talked about the media. Well, when he gets the media straightened out, I want to know about it, because I've been fussing about that for a long time--not because they write about the gory and a lot of anecdotal things, but because they don't even balance anything with what is good under the sun, it seems to me. If that's a negative comment, so be it. We don't know where to go; we don't know how far to go.

First of all, we weren't funded all that well, which is the usual case, but at least we can start on a program. I know Representative Shaw will pursue this if we find fertile ground to plow. For example, with fat biopsies or whatever and all sorts of things. We were actually charged with things like genetic screening and epidemiology, the kinds of things you are doing. I think that it is complicated. I think everybody just has to work together on this and try to get answers, and these won't come tomorrow, I don't think. I think it's up to the veterans groups, really, to try to help the scientific community in terms of this business of the media and so on. If you all are convinced that the scientific community is, in fact, really trying, and I think they are, maybe a little later than they should have but I'm convinced. I don't think I have anymore to say. Thank you for including us.

DR. SHEPARD: Thank you very much Dr. Bernstein and as I said earlier we will be meeting with state representatives in my office this afternoon to discuss our programs and problems in more detail. I appreciate your comment, sir, and we do

pledge ourselves to working in cooperation with the states. Next I'd like to have Mr. Joseph Brett of the New York Agent Orange Commission to bring us up-to-date on some of his activities.

MR. BRETT: STATE ACTIVITIES - NEW YORK. I'd like to thank Dr. Shepard for inviting us down here and I'd also like to thank him for calling me George Brett earlier this morning.

DR. SHEPARD: Excuse me, I'm sorry Joseph.

MR. BRETT: Thanks the nicest compliment I've received since I've taken this job, and I guarantee I'm not going to go on strike. I think a round of applause should go to Mr. Shaw and the Texas delegation. We in the State of New York applaud that legislation in Texas. It was a nice piece of legislation that tied up all the pieces in a nice way and we look at that very admirably. To bring everyone up-to-date on the State of New York, there's a Temporary Commission on Dioxin Exposure which was created by the New York State

legislature by unanimous vote and enthusiastically signed into law by Governor Carey. The commission consists of nine people: five of whom are Vietnam veterans; two representatives from labor unions, one private, one public; a business representative; and the Commissioner of Health for the State of New York, Dr. David Axelrod. The commission was designed to basically determine the state-of-the-art as far as the scientific, medical, legal literature is concerned, and, at a point, to disseminate this information to primarily the Vietnam veterans and other people in the state who are interested in the herbicide issue. In doing that we've conducted public hearings. We have three more left in the state, we've done four as of today, and we're pleased that Dr. Young and Dr. Shepard will be in Albany for our hearing on the 19th of September. At a point in time, I believe in March, we'll have a final report to the New York state legislature with recommendations. We'll also be an outreach program to provide information to veterans primarily, and other people, about the issue of dioxin, what is being said about it, what is being written about it.

We're also going to include recommendations where people can go to get assistance, the VA and other places in the State of New York including private non-profit organizations and hospitals, just where people can go to get assistance if in fact they have the illnesses that we have heard about from testimony at the public hearings. We will provide information about where these illnesses can be treated in the VA and outside the VA, for themselves, their wives, their family and their children. It's a pretty difficult task, hopefully we can pull this off next spring. But I would just like to say that's basically what we as a commission are doing. Also in the law that created our commission, the health department in the State of New York was mandated to do epidemiological studies which they are now doing, and I believe they are working in close cooperation with Dr. Shepard and the VA and we appreciate that very much. I'm very much looking forward to the completion of these studies. A proportional mobidity study is being conducted by the health department. They are also doing a soft tissue sarcoma case study and they're also examining the Department of Transportation workers who sprayed herbicides,

primarily 2,4,5-T prior to its ban. So those three studies being conducted by the State of New York should hopefully help the whole scientific community in addition to the people in the State of New York. So we're very much looking forwarded to their completion in 1983. I think that's basically it, but I would just like to thank again Dr. Shepard. We get reports from these meetings and they're tremendously enlightening, I know to me, and to the other members of the commission. I've heard Wayne Wilson's testimony and Dr. Bernstein's testimony here and other testimony from veterans organizations about the publicity aspect. We're trying to get the truth to the people we're trying to get help. They are not receiving it from the VA, or so it seems to me. I reiterate what has been said by the people from New Jersey and Texas and wherever that the weakness in the system seems to be at the front line, in the hospital level, where people are trying to get treated and the message is just not getting through. I know the sincerity of this panel and I know the sincerity of the people trying to help, but it's somehow not filtered down to

people who are actually trying to get that help or to the VA staff. I believe therein lies the biggest weakness or the biggest breakdown in this communication network, and I think it's happening right at the VA facility level. The testimony overwhelmingly indicates this from the hearings that we've had, and I know from other people from other states. But I thank you again for allowing me this opportunity to speak and I'm looking forward to working with other states and with the VA and hope we can assist those people who obviously need it. Thank you, Dr. Shepard.

DR. SHEPARD: Next I'd like to call on Mr. Michael Leaveck from California to bring us up-to-date in terms of legislative initiative in that state.

MR. LEAVECK: STATE ACTIVITIES - CALIFORNIA. I'd like to thank this committee for the opportunity to be here today and also indicate that my remarks will be brief. I will particularly echo what the past two speakers have said and to emphasize that I think there's a great problem not only in PR but in terms of the credibility of the VA with the veterans

out there and that's what overwhelmingly was indicated by our series of hearings that we just concluded. I just can't emphasize how severe that is. I flew in on the "Red-eye Special" and read a few notes. I planned to be here a little earlier yesterday to talk to Dr. Shepard in advance of this meeting, but the bill, that was partially the subject of our hearings recently concluded in California, was in the first policy committee of the Senate yesterday. That's where it died last year, so I'd thought I'd better stay around and give it a boost. I'm very pleased to report that it did pass that committee without a negative vote, and I think it was largely due to the momentum and clarification that various witnesses provided us, in particular Texas representative Larry Shaw. You've heard many of the same stories that Mr. Brett talked about--much evidence of high level concern. I don't think there's an issue more pressing within the Vietnam veterans community right now. It's a severe level of concern. Our bill was written by an assembly member by the name of Patrick

Mullens. AB 14 might help you. He actually wrote the bill before the present Select Committee on Veterans Affairs was reformed in April, and he wrote the first bill which died last year, which this is essentially a reprint, before the first Committee on Veterans Affairs was created last June. What it provides is information and outreach efforts and aggressive representation and referral for veterans who are concerned about the possible health effect of Agent Orange. It also provides for a review of the literature, an independent review of the literature by our Department of Health. As far as our series of hearings, we're a select committee so we are charged with investigating fact-finding an issue area; we're not really supposed to be concerning ourselves with the bill. It just so happens that most of the members of our committee were very supportive of the bill and wanted to see how the issue would reflect on what we're trying do through legislation. I think we still have some additions to our efforts such as what Texas is providing through actual health screening. There's one suggestion that I have and I fear that our series of hearings on that one particular day touched off a controversy. I think I

remarked to Larry a couple of days after our hearing that probably the most significant thing that happened in terms of political consequences might have been Dr. Spivey's remarks. My observation turned out to be quite accurate. I would suggest a very careful, in a very critical review of that study design. I think the veterans sensitivities and willingness to believe in the results of that study depend on that. Thank you very much.

DR. SHEPARD: Thank you very much, Mike, and I'm looking forward to our getting together later on today. Wayne Wilson is here from New Jersey. Wayne, if you would care to join your state colleagues, I'd be happy to have you do so at this time. Mr. Wayne Wilson is from the New Jersey State Agent Orange Commission.

MR. WILSON: STATE ACTIVITIES - NEW JERSEY. If you recall several months ago I was here, and I was somewhat critical of some of the things we had found in New Jersey. In an effort to be fair, I would like to come back to you today to say that we have seen some very positive progress in terms of the VA facilities in the New Jersey area and that

includes Wilmington, Delaware, and Allentown, Pennsylvania. A few weeks ago we were hard pressed to find enough VA facilities to examine all of the veterans that wanted to be examined in a very short time period. In fact I called for an examination myself in Allentown, Pennsylvania for the veterans in the western part of our state so that they could utilize that facility. There was a 10-week waiting list since they only did one exam per day. We sought the assistance of the American Legion National Headquarters in Washington and are pleased to report that Allentown will now try to do as many as five exams per day and no veteran will have to wait more than three weeks to be examined. We had a problem with the East Orange VA facility. I can tell you that they have increased previously were doing. We're pleased to see a good effort at the Wilmington VA hospital. They have assigned a registered nurse down there as an assistant Agent Orange coordinator. We're getting just fantastic reports on her sensitivity and her working with veterans. I think, as Joe said and some of the other state

state people said, on the front lines in the trenches, if you will, out there where it really happens, these kinds of positive steps I think get out to the veteran very quickly and they see these things. I think that will help make everyone's job a lot easier. I also want to say that we have recently received another computer tape with names and addresses from the Veterans Administration. New Jersey has set the precedent there, and I would imagine that names and addresses of Vietnam veterans are available to your state commissions also. We will soon go out with the first mailing of 22,000, and I would hope by the first of January we will have reached what we hope is the vast majority of our 80,000 Vietnam veterans. In terms of information and assistance, we've been refunded. Our legislative mandate has been extended for a year. We are forming an in-state committee to visit our Department of Health and Environmental Protection so other state agencies can look at some other areas so that the state as a whole can assist its veterans. I still think there is a lot to be done.

Some of you will be getting mail from New Jersey veterans. We have put out a new self-help guide. Rather than me writing Dr. FitzGerald or Mr. Brett all the time, I think, we will allow our veterans to write Fred and Bob directly. I think we may be the most militant of all the states. But you know Joe Brett made a comment today, and I just want to echo his comment because I think he's absolutely right. You know I'm critical of the Veterans Administration for sure, but at the same time I had a Professor Solomon that told me, "Wayne, do not be critical unless you can make some positive suggestions to improve what you're saying." I think that's our intent, we're critical but I think we make some positive suggestions at the same time and I don't think the problem is right here. I happen to think that Barclay Shepard is a good man and I happen to think the intentions of this committee are quite honorable, but I think we're got some blue birds out there in the field and I'll say it again, if they want to go to Fairbanks, Alaska and not serve veterans we'll certainly help them. It's a complex and serious problem, and again, I'll say the urgency of veterans and their families feel is just, it's there and that's what it's all about, the

bottom line. Thank you very much.

DR. SHEPARD: Thank you Wayne, we appreciate your comments. Let's take about a 6-minute break and then reconvene promptly, because we do want to address the questions and concerns from the audience, it's part of our process. If you have questions from the floor that you would like to address to members of the committee would you please write those questions down and pass them forward.

(A brief recess was taken)

DR. SHEPARD: COMMENTS AND DISCUSSION OK, we have one question which is as follows: Many Vietnam veterans have had previous, I think the word, is "inadequate" Agent Orange physicals, will these men be notified for re-examinations according to your new guidelines?

I think that any Vietnam veteran who was dissatisfied with a previous physical examination is perfectly welcome to request a second examination either at the same facility or another facility as he wishes. There's no limit on a Vietnam veterans requesting an examination so I would suggest that any Vietnam veteran who is, was dissatisfied with his

first examination apply for another one. In answer to the question, will these men be notified for re-examination, I'm not sure how we would identify those individuals who are dissatisfied in order to notify them. I would just simply suggest that anybody who is not satisfied simply ask for re-examination and proceed from there. There are no specific guidelines for a normal process of reexamination, at the present time. Let me just state that the purpose of the registry is to identify any Vietnam veteran who is concerned about possible health effects of exposure, to get some information on them, and store this information in a computer data bank. It is not a research tool, it was a never designed to be that and it is not anticipated to be that. That doesn't suggest that there might not be some interesting information that would result from an analysis or an examination of the data results that has come forward from these examinations. Obviously, we are very interested in what these examinations are showing. We are now in the process of looking at that information in some detail. I guess it's Bob Conerly that asked that question, does that answer your question, Bob?

MR. CONERLY: Not really Dr. Shepard. My name is Bob Conerly, I'm with the local chapter of Vietnam Veterans of America. We've had guys request re-examinations only to have their records go from adjudication back to the VA hospital and in time have another year wait to find out if their first physical has meant anything. In many instances these physicals were requested at the VA level by doctors who have been working with these people and they have not gotten them. It just seems like it's a big waste of time to go ahead and request another physical when your file is going to be pulled directly out of adjudication and sent back to the back of the file. That's how it's been explained to me and I was just wondering if, you know we've all gone through this before, why can't you take the people who have had these physicals and re-evaluate them because in most instances the fellows here in the district have never gotten their sperm work or have never gotten blood work, adequate blood work, have never had a liver biopsy and it's just a continuation.

DR. SHEPARD: OK, let me clarify a couple of those points. It is not part of the VA policy to do routine sperm examinations. The sperm examination question has come up

and it's left to the judgement of the physician as to whether or not that's an indicated procedure. Certainly a liver biopsy is not a routine test, so if it's on the basis of a failure to do a sperm count or a liver biopsy, these will not constitute an inadequate examination. It was never intended that it be a part of the routine examination. So maybe that will be helpful to you. I want to re-emphasize that the Agent Orange registry is not directly connected in any formal way with the claims process. A claims examination, or a so called C and P examination, does not constitute an Agent Orange registry examination per se nor is the reverse true. They are really separate processes. Now, it's possible that somebody who comes in for a C and P exam for a claims adjudication process, and identifies himself as a Vietnam veteran--it's possible that the examination is accomplished at the same time. But applying for a claim or making application for a disability claim is not the same thing as applying for Agent Orange examination or vice versa. And I recognize that has a really confusing point and we've tried to clarify that. We encourage all concerned Vietnam veterans to come in for an Agent Orange examination. We try to make

it very clear to these individual that requesting an Agent Orange examination does not constitute filing a claim, that if he wants to file a claim that has to be done as a separate step. Now it's possible in some instances that the physical examination part of that process is one in the same although it's not intended to be specifically one in the same.

MR. CONERLY: Yes sir, well they do that down here, that's just one of the points that we find most distressing especially with our members who have been waiting sometimes three years for re-examination. We have members out here right now that don't know where they stand at all with the VA. Every time they make a phone call to find out at the hospital they're told to call adjudication and you can't get a phone number for adjudication so you have to write them a letter. As soon as adjudication gets the letter, they take their file out of the adjudication system, send it back over here to the hospital and then the man has got another year's wait. That doesn't sound very helpful to me, I mean it's

just not a very good working system.

DR. SHEPARD: Why don't we look into that for you and see what the problem is. I'm still not exactly sure where the problem lies and I just want to say that when you're talking about adjudication, adjudication has nothing to do with the Agent Orange examination per se, it's a separate program.

MR. CONERLY: OK, thank you.

DR. SHEPARD: But, I'd be happy to talk to you and try to get to the bottom of the problem.

MR. CONERLY: OK, thank you, Dr. Shepard, thank you.

DR. SHEPARD: Wayne Wilson sent up a question for Dr. Erickson. Given the urgency, veterans and their families feel on the subject of birth defects, is there anyway that the study timetable can be shortened, i.e., monies, other resources, etc.?

DR. ERICKSON: Not at this point in time. No there is no way to shorten the study. The data collection will take place over a period of approximately 16 months, I believe. That the latest projection. There is a lag time which we don't feel we'll be able to shorten because of expected problems in tracking people. If we were to close out the study too soon then we might not find all the people that we would like to find and that might introduce inherent biases into it. Beyond the collection of the data phase we'll be allowing ourselves six months for analysis and reporting of the data and might be able to shorten that down a little bit. I think we've given ourselves a pretty tight schedule on that. The length of the study has nothing, at this point in time, will have nothing to do, with availability of finances but simply as I say mainly in matters of tracking people.

DR. SHEPARD: I'd just like to echo that. I know from my personal experiences in dealing with this whole issue that it does take time to properly put together a study and go through all the clearances that have to be accomplished and then to simply gather the data itself in a scientific matter, it simply takes time. I don't know of any way to

shorten that time, it's admittedly very frustrating. When you talk about a 10-year study, that sounds like forever, but some of that 10-year study is to look at long-term effects and you can't get long-term effects in a short time. I mean that's quite impossible. I think, the CDC study has got to be conducted in a very careful detailed manner. Part of that is administrating a very complete questionnaire and part of the processes of administrating a questionnaire is to get OMB clearance. All of these steps take time and I'm happy to report that Ranch Hand study and the CDC study both have gone through this clearance process and are now just waiting for the mechanics of the administration of contracts to be completed.

Are there any other questions? Yes, Mr. Lewis Milford, oh excuse me, I'm sorry, I didn't see this question. Is the VA willing to quickly supply the names and addresses of Vietnam in-country vets to those states and/or veterans group which wish to conduct outreach programs? If the Department of Defense has records, will the VA aggressively encourage DOD to do so?

That's a complicated question and I'm not sure that I have all the answers. I know that, excuse me, the question is not complicated, the answer is complicated. Getting at records of individuals especially by state location is a difficult job and where you say "quickly," my answer is "probably not quickly." Now that isn't to say that it can't be done. It's gratifying to hear Wayne report that the VA is supplying to the State of New Jersey, the names and addresses of New Jersey Vietnam veterans. That is not an area that my office handles so we're not directly involved in that process, but we can certainly get the answer for you, and I'll be interested to talk to Wayne to see what steps we're taking to accomplish that and obviously that's very important. The Department of Defense records, I don't think that the Department of Defense has those records available to state and again that is not my area of expertise, particularly, but is Jerry Bricker here? Dr. Bricker from the Department of Defense was here earlier (he's in the hallway) Is he out there now? Could you ask Jerry if he's willing to come in? He is particularly skilled in this area. This is part of his responsibility so maybe he can answer that question for you. While we're waiting for Dr. Bricker to come in, I would just like to clarify a potential misconception that may have

been made in the matter of the VA delay in initiating the epidemiology study. In addition to the temporary restraining order that was sought and denied, there was a long GAO review of that protest. That didn't get mentioned this morning and I just want to say that the Veteerans Administration was not at liberty to initiate the design of the epidemiology study due to the fact that the whole process was under review by the GAO. We were given specific, it's my understanding, that we were given specific guidance not to initiate that effort until after the GAO report was cleared. Yes, Dr. Bricker, a question has been asked if the Department of Defense has the records, will the VA aggressively encourage the DOD to supply this information to states and/or veterans groups. Now these are records of Vietnam veterans by state. I have said that it's my understanding that the Department of Defense does not have records of Vietnam veterans by...

DR. BRICKER: No sir...

DR. SHEPARD: So therefore...

DR. BRICKER: In my department, to the best of my knowledge, all records are essentially contained in your basic 201 file filed alphabetically. The critical elements that are needed to locate such a file would be: name, and

service number, which in some cases is your SSN but not in all cases. Prior to certain dates in the various services they used another type of serial number such as FR19699A. Their date of birth and place of birth will finally absolutely locate the individuals to be sure we have the correct John Smith or Al Jones.

DR. SHEPARD: Do you know anything about the process by which the New Jersey State Commission was able to get New Jersey Vietnam veterans? Wayne Wilson mentioned the fact that had been done, and I'm gratified that it has been done because I know that's been one of the bones of contention, but I'm not sure of the process, do you get involved in that at all?

DR. BRICKER: No, I'm not familiar with that procedure.

DR. SHEPARD: We can find that out. Is Wayne here?

MR. WILSON: I'm still here.

DR. SHEPARD: Certainly we can discuss that this afternoon at our get-together. It will perhaps be of help to other state organizations to find out the procedure. Wayne?

MR. WILSON: Yes.

DR. SHEPARD: You mentioned earlier that you now have a list of names and addresses of Vietnam veterans from New Jersey?

MR. WILSON: We have, yes, we have 20, the VA has approximately 39,000 Vietnam veterans and some era veterans, the ones the computer pitched, but we've got our first 22,000, and I believe the next increment of 1,700 will be forthcoming in about four weeks.

DR. SHEPARD: Do you know who you were dealing with in getting that information?

MR. WILSON: We dealt with the Controller, Mr. Hoffman. The legal section staff group #4 made the decision that we were in compliance with the law. I will be willing to share those letters of communication, in terms of compliance, that you need to have, with anyone.

DR. SHEPARD: I thought maybe we could talk about that in more detail this afternoon. Does that answer your question Mike?

DR. SHEPARD: OK, are there other questions from the floor? Mr. Lewis Milford of the National Veterans Law Center.

MR. MILFORD: As Barclay said, my name is Lewis Milford, I'm with the National Veterans Law Center and I'm also on the faculty of American University of Law School. I guess, thirdly, and probably in the eyes of some, one of the alleged collaborators which joined first in creating the press hysteria on this issue. I'd like to make one remark at the outset before I ask you a couple of questions about the Dr. Spivey comments. The first has to do with the GAO report. I was a lawyer on the GAO protest and I supported what Jon said, that the advice that the agency was given, not to award that contract, was the advice of it's general counsel. It was not an instruction on behalf of the General Accounting Office or on behalf of any one else, so that it was an agency decision not to award that contract in light of legal issues. What I would like to do is ask a couple of questions about Spivey remarks because I think they are very important. It's one remark that I would like to

emphasize, I've noticed that Dr. Spivey made before the California State Assembly and it's as I understand they were unsolicited remarks before the State Assembly that the only issue he was asked to testify about was the California Bill and that all these additional remarks made about the VA epidemiology study were those that were not asked for and in fact were his own, without any question from the California State Assembly. It's this quote and it's this by a scientist who has yet to conduct a study and that is to...

DR. SHEPARD: Design a study.

DR. MILFORD: Design a study and I quote, "the fear which is generated by the current publicity is very likely to be the most serious consequence of the use of Agent Orange." The main question I have, and it's to Dr. Shepard, is whether he considers the statement appropriate to be made by a scientist who has been hired by the Agency to ask the proper questions about Agent Orange?

DR. SHEPARD: Well, obviously I think that, at perhaps in retrospect, was an unfortunate statement, and I think that perhaps Dr. Spivey would agree to that. I was not aware that Dr. Spivey was going to testify until the day before, and I think that it was unfortunate. I think that probably his statement is a true reflection of a personal opinion that he may have based on his current knowledge of the literature, his understanding of the total matter of the toxicological effect, and so forth based on the information today. There seems to be a wide diversion of feelings, impressions, beliefs. The study is mandated and is necessary in order to determine whether or not there is, in fact, a scientifically valid, statistically valid problem. So that although it may have been an unfortunate comment in retrospect, I don't see that it is in any way going to adversely impact the conduct of the study, and to further elaborate on what Dr. Brick said earlier, this is not a one man study. This study was designed by a group of individuals of which Dr. Spivey was one and it is going to be subjected to an intensive review by

a number of scientists. In fact, if there appears to be a bias in the design and that should be readily apparent, that will be brought to light. So that I think, I would hope, that those of you who represent serious organizations would make that point very clear. The design will be subjected to an intensive review. You are invited to be a part of that review. So I hope that any concern of any group that the study will be biased based on Dr. Spivey statement, it just isn't likely to happen.

MR. MILFORD: If I might ask a follow-up question. Has the Agency taken any actions to avoid these kinds of statements in the future by Dr. Spivey, particularly in light of the serious issue of credibility that almost everyone here has addressed?

DR. SHEPARD: Well, if your question is have we reprimanded Dr. Spivey for having made that statement, I have not personally discussed the issue with Dr. Spivey, largely because I have been in travel status. I'm sure that the

issue has been raised, and I think it is safe to assume that we would hope that Dr. Spivey would not be placed in a position where it is likely that statements of this kind would be made. I will personally speak to Dr. Spivey and encourage him to refrain from the statements of this type.

MR. MILFORD: If I may ask one follow-up. That is that the distinction was made between the design and the conduct of the study. The Agency has not decided who will conduct the study. It has also been said that perhaps bias in the conduct of the study is the most serious problem to be avoided. Has the Agency made a decision or will it make a decision that Dr. Spivey will not conduct a study, given the unfortunate statements that he has made?

DR. SHEPARD: Your question implies that our decision to give Dr. Spivey the responsibility of the conduct of the study will be based on his statements. It will not be. As we have said publicly on a number of occasions, the decision

as to who will likely conduct the study will be a follow-on decision to the review of the design of the study. During the review process I suspect that discussions will be involved as to the most appropriate body to conduct the study. My personal guess, is that no one group will conduct a study of this magnitude. It would be very difficult to conceive a group conducting the entire study. I think that the VA should be involved in the conduct of the study. I think that large parts of the study will be done by contract but I think that this is just my hunch--the VA will play a role in monitoring the conduct of the study. Now, this isn't to say that it will do it alone, obviously.

MR. MILFORD: I'm not sure that your answers are responsive to the question. Do you consider the statements grounds for excluding Dr. Spivey from consideration on the conduct of the study?

DR. SHEPARD: I just can't answer that question, Lew. I don't know that Dr. Spivey or anybody else considers that they would be the most appropriate person to conduct the study.

I don't think that there is anything in the thinking process at the present time that makes it likely that Dr. Spivey or any of his colleagues will actually conduct the study. I'm not enough of a research scientist myself to know whether or not precedence exists for one group to design a study and another group to conduct the study for the purpose that have been addressed here. I think that is entirely appropriate to have one group of individuals to design the study and another group to actually conduct the study, which perhaps strengthen the whole question in credibility. I hope that I answered your question but I suspect that I haven't completely and I'm not sure what the answer is at the present time. Yes, Dr. Hodder.

Dr. HODDER: This may comment on your asking for someone to be totally unbiased in designing scientific study. It seems like there is a catch-22. If you have someone who is baised against what you want, then, of course, you are concerned that he would do it fairly. If he's biased for you, then obviously the people representing the other camp would

feel same way. If the person were totally neutral you, he wouldn't want to do the study at all. The scientific process should take care of this. I don't think that any scientist who goes into do his study goes in without some personal opinion, but the methodology of the science, and the review process that Dr. Shepard has talked about, is what is the protection against bias, not the person himself. You don't need the protection against bais to be based on the individual being totally neutral; rather you set the process up against bais. For example, one of the techniques would be to allow the slides in a pathology study to a pathologist to evaluate them with absolutely no knowledge of which slides are the case and which slides are controls. Now, he may have a very definite opinion as to whether a factor does or does not cause a disease, but if he doesn't know what is in a case or control, his bias is unimportant...because it can't affect the result. So that's what's important to a design to my way of thinking, is can we blind the investigators in such a way that their individual opinion, is whether they are pro or con, will have no effect and I think that's the real issue. That is important, not whether the person who originally wrote it up felt pro or con.

MR. MILFORD: Ok, if I may recast the issue, we're not asking that someone take a position in favor of the veteran and say I can do the study. What we are asking is that someone before the study begins not predict it's outcome. That's the problem. We are not charging that he is biased in favor or against, but certainly what this does suggest is that he had predicted the outcome before the results are in. I think that that's an irresponsible statement, and I think most people, most veterans, will feel that cancer and birth defect and the other health defects were certainly more serious than fear.

DR. SHEPARD: Any further comments? Yes.

DR. MURPHY: Well, just in connection with that, was the a statement that fear is most likely to or may be the most serious problem faced by exposed veterans? The fear which is generated by the kind of publicity I've is very likely to be the serious consequences of the use of Agent Orange.

I certainly would defend the proposition that you can't go into anything totally unbiased. If you have a hypothesis, which is what scientific research is based upon, you have some sort of a bias based upon what you believe to be the facts. At the time, you may be wrong, your hypothesis may be wrong.

MR. MILFORD: I must say these were written statements that were prepared for the committee and presumably were thought out before the hearing.

DR. SHEPARD Thank you. There is one other point that's been brought to my attention. I should have said earlier and it's my impression that we have a letter from the Comptroller General requesting that the VA not proceed with the with the awarding of the contract until completion of the GAO review. I am sure that you are aware of that. Now, whether that's interrupted as being a directive, obviously, we're talking about two branches of government. The Comptroller General cannot tell the VA what to do and it may be twisting on that legal issue that your point in being made.

MR. MILFORD: You would probably have the same lawyers' disputes there that we're seeing with the scientists here.

DR. SHEPARD: The VA was not totally at liberty to proceed with the award of the contract, I just want to make that point clear. Are there any other questions, comments from the forum? Well, we thank you very much all of you, the members of the committee and patient attentive audience for being part of the discussion. Thank you very much.

☆U.S. GOVERNMENT PRINTING OFFICE: 1982 381 487 3606

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

**(Tenth Meeting
November 19, 1981)**

April 1982

Washington DC 20420

VETERANS ADMINISTRATION

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ADVISORY COMMITTEE ON HEALTH-RELATED
EFFECTS OF HERBICIDES

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Veterans Administration
Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Thursday, November 19, 1981

The Committee met, pursuant to notice, at 8:30 a.m., BARCLAY M. SHEPARD, M.D., Chairman, presiding.

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I N D E X

P R O C E E D I N G S

(8:30 a.m.)

CALL TO ORDER AND OPENING REMARKS

DR. SHEPARD: Let me say how delighted I am that you, the members of the committee, have showed up in force today. We are very pleased to have you all here and, also, some familiar faces in the audience and some new faces. We are all very happy that you could be with us this morning.

I have just a few brief announcements.

Dr. Jack Moore, who is well known to many of you, has submitted a letter of resignation from the committee. We are very disappointed that that was necessary. However, we certainly understand because of Dr. Moore's very, very busy schedule.

He will, however, maintain a very close relationship with the whole Agent Orange effort in that he will chair the newly constituted advisory committee for the Ranch Hand Study. We are most delighted, because of his ongoing interest and expertise in this area, that he will maintain that relationship. So we are very pleased. Although we'll lose him as a member of this committee, we are happy that he is maintaining his active participation.

We are going to be hearing from our new Deputy Administrator Designate, Mr. Hagel, shortly. I am very happy that he will be with us this morning.

He will be taking a very active interest in the VA's effort in the Agent Orange issue and is also going to be the principal representative of the Veterans Administration to the Agent Orange Working Group, so I'm looking forward to his comments this morning.

Many of you are aware that we have recently completed our Literature Analysis. Some of you, I suspect, already have copies. Members of the committee were supposed to have been sent copies. In the event that they haven't received them, let us know, or if there is some problem with them.

We will have a limited number available for those of you who have a need for them. We are negotiating; that is, the VA is negotiating with the Government Printing Office. Hopefully, they will be printed and distributed and made available through the Government Printing Office but we still have some copies available here.

Many of you were aware that we had an interesting hearing yesterday. Senate Veterans Affairs Committee held oversight hearings on the progress of research activities related to the whole Agent Orange issue. I suspect we will be hearing more about those during the course of the session this morning.

Mr. Hagel was there for the Administrator's presentation, and he may make some comments about those hearings.

They started at 9:30 in the morning and went on until about three o'clock in the afternoon, and I must say I was impressed with Senator Simpson's presence throughout virtually all of the hearing in spite of a very busy schedule.

There is no question, I think, in anybody's mind who was there, that he has a deep personal commitment to helping in any way he can, through the efforts of his committee, to bring this whole issue to a reasonable resolution.

I have just a few housekeeping notes. Those of you who have questions, please write them down on cards and give them to Don Rosenblum, who will bring them forward. We will devote a portion of the agenda to answering questions, following completion of the formal agenda.

The entire conference this morning is going to be transcribed, as it has in the past. Those of you who have questions from the floor at the end of the meeting, if you will please come forward and use one of the microphones so your question can be recorded.

I might, while we're waiting for Mr. Hagel, move into the agenda on the subject of a revision to the Agent Orange Registry.

We have been working hard in our office, trying to make some improvements, some streamlining efforts, in the Agent Orange Registry process. We have now examined some 68,000 veterans, and we're looking at the data which that

process has generated.

We have made some observations, some tabulations, but one of the things we've found is that the way the information has been encoded does not make it very convenient for tabulation. Also, there is some information there that we think, probably, is not very helpful, and there's some information that isn't there that would be very helpful.

So we are now making a major revision to the encoding system and the data-gathering process. As you can imagine, it's a fairly heavy job to make this kind of revision in the face of an ongoing process. But what I would like to do is, between now and the next meeting, we will hopefully have the changes in a readable and reviewable form and we will submit those to the members of the committee for their review and comment.

We hope to have those to the committee in the next few weeks so that you will have a chance to review them, comment on them, and then we can discuss them at our next meeting.

I see Mr. Hagel is arriving right on time.

Why don't you come up here, sir.

I'd like to introduce to you, Mr. Charles T. Hagel, the Deputy Administrator Designate, who himself is a twice-wounded combat veteran of the Vietnam War and, as I indicated earlier, will be taking a very active role and has already

done so in the Administration's dealings on the Agent Orange issue.

Mr. Hagel.

REMARKS BY DEPUTY ADMINISTRATOR DESIGNATE

MR. HAGEL: Thank you very much, Barclay.

Good morning. I appreciate, very much, an opportunity to welcome you here and especially say thanks to each of you for your efforts and contributions that you make on behalf of all our efforts, the VA being just one part of this, to try and find a solution to this elusive problem of Agent Orange and what effects there might be as a result of exposure to Agent Orange on our military personnel who were exposed to it.

As Barclay said, I spent a year in Vietnam, myself, in 1968, with the 9th Division in the Mekong Delta. My brother was with me that entire time and I stay in touch with many friends who shared that experience with me so I, number one, have a very personal commitment to try to find a solution to this issue. So that's number one.

Number two, Bob Nimmo had asked me a couple of months ago, when I came over here, if I would be willing to accept a major role in the Vietnam veteran issues specifically and -- Agent Orange obviously being the most pressing, the most emotional, the most volatile of all those issues, and I accepted that role.

As Barclay said, too, Bob Nimmo had asked me to be

chairman of our Agent Orange Policy Coordinating Committee, which I have done, and have gotten to work with some of you, and I know we'll have an opportunity to work with most all of you before not too long.

I especially want to thank you all for your efforts in helping us with this even, it seems, more elusive a question of trying to come up with some kind of a workable protocol so that we can move on and initiate a study that will try and gap some of the distances here between what's real and what's not real.

That's been a long, difficult road, I understand, and each time we meet -- and it's been almost on a daily basis the last three weeks -- I understand a little more clearly the problems associated with this issue. So I know it's difficult and, again, I appreciate your time that you invest.

I think Barclay will or has, and the rest of our people will give you an update on where we are now and where we're going to go as a result of the events of the last two weeks, specifically the decision that we made considering the initial design protocol that UCLA came up with. And I don't want to get into that because that's really the professionals, like Barclay's area.

But I do want to say, again, I appreciate your coming and giving your time.

I think--generally, for those of you who were not

present yesterday or did not hear much about that Agent Orange testimony, I thought that it was as productive a forum as you can have considering the politics of the issue, the emotionalism of the issue.

We intend here at the VA, under Bob Nimmo's leadership, to press this issue as far as we need to, to get the answers we need to get. Whatever that takes resource-wise or political-maneuvering wise or whatever maybe we haven't done in the past, we intend to do it. So there will be no holding back on trying to get an answer and we'll be open about it.

I am available to talk to any of you. Bob Nimmo is available to talk to any of you. So just understand that and know that, and that we're all trying to work together to find an answer to this problem.

Other than that, Barclay, I don't have anything else. Just to say again, I'm personally flattered to be associated with all of you. I know a little bit about some of you from what Barclay and Larry Hobson and Al Young have told me. I think it goes a long way in talking about the Veterans Administration, which I am very proud of. It's not that we don't have a problem or two, but I'm proud of this institution and we're going to try and make it even better. I think it goes a long way in talking about the credibility of this institution to have people like you helping us.

So, with that, any questions you've got, I'd be

very happy to answer them.

Thank you, Barclay.

DR. SHEPARD: Thank you very much. Feel free to stay as long as you want. I know you're busy.

MR. HAGEL: No, I'd like to actually just stay a few minutes and get a feel for it.

DR. SHEPARD: Sure, fine.

Since you brought up the subject of the Epidemiological Study, I think we may digress from our agenda a moment. Since this is an issue of immediate interest, I might just amplify a little bit on what Mr. Hagel has just alluded to and a decision that's been just recently made in the last few days here at the VA.

As many of you know -- and let me start off by saying how much I appreciate all of the efforts of all of you who sent in comments on the submitted protocol design. We, for a number of reasons, made the decision that based largely on the comments that came in from the various reviewing groups that we don't in fact have a usable protocol and that major modifications or amplifications need to be made before we can really grapple with the details of the protocol in order to make a meaningful review.

Therefore, we have made the decision that what was submitted does not qualify as an acceptable initial design as was spelled out in the contract, an acceptable initial

design for review.

Consequently, we will now forward in a formal way, to the UCLA investigators, the comments of the three reviewing groups, and in that forwarding process we'll outline very clearly what we expect at the next submission so there will be no ambiguity about that. I'm not suggesting that there's been a lot of ambiguity about it to date, but there may have been some.

So starting about the middle of the week, next week, the UCLA group will have 35 days in which to come up with a preliminary design in accordance with the contract, which will then be submitted to the review groups which have already taken a look at what was submitted. Then the contract will call for a 30-day period in which a final revision modification will be allowed.

In essence, what this does is extend the contract for a period of 35 days.

I'll be happy to take any questions on that, as they may occur to you during the course of the presentation.

Dr. Hodder is on the agenda to make any comments.

Dick, as long as we're talking about that, why don't you take that now, if that's all right with you.

DR. HODDER: All right.

DR. SHEPARD: Please get close to a microphone since we are recording this.

DISCUSSION - EPIDEMIOLOGICAL STUDY

DR. HODDER: I won't make any formal comments, really. I think most of the members of the subcommittee have copies of the comments submitted, with my summary on top of them.

I think, basically, the overriding feeling was that this was not really a protocol that could be judged. It had to go back to the author and either have specific methods laid out or the reasons why those could not be laid out submitted.

For example, if the exposure index couldn't be defined in detail, then at least the process needed to fulfill that part of the RFP ought to be laid out.

Also, many reviewers noted that a lot of the assumptions and definitions were not adequately spelled out. I think that's obviously based on comments made yesterday as well as the action taken by the VA. Obviously, the decision has been made to simply go back to the authors and give them an extension of time, realizing this is a two-year process, to give them 30 more days to try and put this together.

DR. SHEPARD: Thank you, Dick. I want to say again how much I appreciate your efforts in pulling the comments together.

I hope that all of the committee has received a copy of the proposed committee report. I was able to contact many of you who had submitted comments to see if you were in

agreement with Dr. Hodder's memo dated November 6th.

If there are any questions, comments, disagreements, whatever, on that regard, I think we ought to deal with those now.

Yes, Dr. Fitzgerald.

DR. FITZGERALD: Barclay, what is being proposed following this 35 days, as far as review by this committee is concerned? Are we going to have an opportunity to get together either as a committee or a subcommittee rather than going through the individual response to you like we did previously?

DR. SHEPARD: Yes, that's a good question, Tom. I think that, based on our recent past experience, it would be a good idea for us actually to get together and meet as a subcommittee to discuss this. I would hope that Dick would be willing to chair that again. But I think that would be a helpful process.

DR. FITZGERALD: I think so, yes.

DR. SHEPARD: Yes, good.

DR. FITZGERALD: Thank you.

DR. SHEPARD: We'll make a note of that.

Yes, Dave.

DR. ERICKSON: As you know, yesterday Dr. Houk said that he felt that 30 days just wasn't enough and --

DR. SHEPARD: We can't hear you.

DR. ERICKSON: I'm making the comment that yesterday

at the Senate testimony Vernon Houk, from CDC, made the comment that he felt that an extra 30 days just wasn't going to be enough time. I would like to second that point of view. I don't think you're likely to get enough detail put together in another 30 days unless they turn the whole School of Public Health at UCLA working on that.

I would like to make another comment, on a slightly different issue, a comment which I made in my own review of the UCLA submission, and that is that I believe there are certain phases of the proposed work which could be done rather rapidly, in particular, a proportional mortality study for which proportional mortality studies have a -- or problems with them, yet they can be done relatively quickly and inexpensively. I think that the VA ought to press on with doing something along that line.

DR. SHEPARD: Fine. Thank you, Dave. Yes, I'll comment on your second point, and I certainly agree. And on the agenda, we do have some time that we will devote to a discussion of the mortality study. Dr. Page is here and will lead that discussion.

In regard to your first comment, we certainly agree that 30 days is inadequate to start with what we have and come to a full protocol. I don't think that's the intention.

I think the intention is that we have a product that will at least outline some of the methodology and perhaps

amplify the whole area of exactly what kind of physical examination, what end points will be looked at, what kind of statistical numbers we need to have in order to draw the conclusions that we hope to draw.

I think, as pointed out by all of the reviewers, that's an area that needs to be firmed up. It's my impression, speaking with Dr. Detels and Dr. Spivey, that much of that information is already in place and it's a matter of getting it out and circulating it.

For those of you who were at the testimony yesterday, Dr. Detels made the point that he agreed with most of the comments that were made by the reviewers and particularly about the lack of detail in terms of some of the end points and also some of the statistical numbers that would be needed to draw conclusions.

He made the point that UCLA did in fact err on the side of ultraconservatism, in terms of revealing what was going to be in the protocol, under the concern that if too much was revealed then it would bias the outcome. I think that it's safe to say that the investigators are appropriately chastened, if that's the word, in that regard and will at the next submission provide much more detail.

But I agree. I think that we will not have a detailed protocol. Certainly, we will not have, presumably, a questionnaire. In other words, we will not have in 35 days,

or even the 30 days after the 35 days, a protocol that we can hand to an investigator and say, "Go forth and do."

But I think we'll have some of the methodology in hand so that we can make a more critical appraisal of what we have.

Yes, Dr. Murphy.

DR. MURPHY: Barclay, what is your view of how soon that you'll get what you are hoping you'll get by the 35 days or 65 days? What is your idea of how this will proceed from there? Will it be another request for bids or a contract, a request for proposals to conduct the protocol to go out, or is the idea that the UCLA group will do or at least coordinate the protocol, or will this be done by the VA, or do you have any --

DR. SHEPARD: I have some thoughts, obviously, and I'd be happy to share those with you.

First of all, I think it's important to make very clear that the contract with UCLA is for their best effort at designing a protocol. That should be completed, hopefully, in the next five or six months at the latest. That includes all the review processes and so forth and a general consensus and a final decision by the VA that this is, in fact, in conformance with the contract, a product that's in conformance with the contract.

Obviously, additional work will have to be done.

It's my view that some kind of feasibility testing will have to be done of the protocol before the study actually gets underway, specifically in the whole area of exposure. That's still very unclear. That's one of the things that we hope the UCLA next submission will clarify to some extent: what they consider an exposure index, how they would establish that exposure index, what use of records will be made, and some indication as to perhaps the resources required to make those determinations.

When that protocol is approved, if it is approved, I would guess that a contract would probably be solicited, for an interim feasibility study should test some of the hypotheses, some of the procedures that I suspect will be outlined in the protocol.

I think that concurrent with that some work such as a mortality study, if that's deemed necessary in addition to what we will be doing here or other parts of the study -- it seems to me that contracts could be let for, for example, the design of an interview questionnaire, if the decision is made to go that route.

So I think that there will be several pieces of the action that could be started fairly soon after the protocol is approved.

The really big, burning question, I think, is should the VA in fact conduct the study; that is, should the VA

remain in control of the conduct of the study? Much as the Air Force is remaining in control of the conduct of the Ranch Hand Study, whereas much of that is being done by contract, the Air Force is clearly staying on top of it with the help of an advisory committee.

Should that same kind of approach be the way the VA does it, or should we go totally outside the agency for the conduct of the study and just, you know, hand it to somebody and say, "Go off and do your thing and come back in five years and let us know what you found"?

I would prefer the former, but I think it's a little premature to say exactly how that will happen. But, hopefully, that decision will evolve as we are going through the review process.

Are there any other questions?

Yes, sir.

DR. FITZGERALD: Economically, you may be forced, of course, to do that. I recognize that. In your considerations, are you also considering having a safeguard to have an outside source to act as a sort of supervisor if the VA, indeed, has to do the study itself in order to overcome the apparent, if not real, conflict of interest?

DR. SHEPARD: I think, very clearly, if the VA does remain in control of the study, that it would have to have an advisory committee, much as the Air Force is having with the

Ranch Hand Study.

That's something we need to be thinking about very soon, I think. In any case, no matter how the study goes, I think there needs to be sort of an overseeing group.

Presumably, even if it's done under contract, it will be a contract let by the VA. So the VA, obviously, will have a vested interest in the process. I think that it would be appropriate and mandatory that there be such an overview committee heading it.

DR. FITZGERALD: One more question, if I may, and that is, one of the big objections that Dr. Spivey and his group brought forth in their proposed protocol was the difficulty they had experienced in getting top-secret clearance in order to get at the Department of Defense records. What is going on now as far as overcoming that obstacle?

DR. SHEPARD: Dr. Spivey and Dr. Detels and, I believe one other of the investigators has, now, clearance so there should be no obstacle for them to gain access to the records.

There are some mechanical problems, obviously. At one point it was suggested that these records should be sent back and forth from Washington to UCLA and that, I think, appropriately has been deemed infeasible. So it seems to me that if they are going to exercise that review clearance procedure,which they now are entitled to, I gather, they will have to be a team here to come to Washington and review

the records.

I think that, from my own view, we need to establish that very soon. I think there is a distinct disadvantage in trying to operate from two different coasts, so I think that, clearly, we're going to have to have some closer geographical linkage. Hopefully, that will evolve soon.

DR. FITZGERALD: I recognize that it's their problem since they are the contractor, but it might be advisable for them to have somebody in that group that is knowledgeable on the accessibility and the mechanics of getting to DOD records.

DR. SHEPARD: Yes, sir. I think that's a very good suggestion and I think that suggestion was made yesterday in the testimony that they should enlist people on their staff that are familiar with DOD records. Thank you.

DR. MURPHY: What is the priority for that, with regard to that group as opposed to whoever might have a contract for conducting the study? I mean, is that a part of the study or is that a part of the design of the study? I think if you say we should do all this, it presupposes a certain contract of doing a study, which-- I'm not sure you want to presuppose that yet.

DR. SHEPARD: I'm not an expert in contracting, but it would be my gut feeling that we would have to have some kind of a modification of the existing contract in order to

accomplish that, to have them actually have people stationed here in Washington, working closely with the DOD records people.

I don't think that is spelled out clearly in the existing contract. Again, I'm not a contracting expert, but my gut feeling is that we would have to make some modifications to the contract to accomplish that.

Are there any other questions or comments on the Epidemiological Study?

All right. I think we'd better move along. Major Brown is with us and we would like, now, to call on him to bring us up to date on the status of the Ranch Hand Study.

Phil.

RANCH HAND STUDY UPDATE

MAJOR BROWN: Thank you, Dr. Shepard.

Since our last meeting, I will bring you up to date a little bit about the Ranch Hand Study. I will not go back and review past history since that's getting rather long.

Just to give you a quick thumbnail, on the 18th of September the Air Force let a contract with Lou Harris Associates for purposes of doing the questionnaires for the Ranch Hand Study participants. The period of performance for that contract is six months. Date of collection is anticipated to be completed by April, 1982.

A request for a proposal for the physical

examination phase of the contract -- for the physical examination phase of the study, rather, was published in August of '81.

We have received three bids. Those bids are being evaluated. We anticipate a selection of the successful bidder by the end of this month.

That contract will have a period of performance for up until September of 1982. With that schedule, we anticipate having our reports made available to us in the time period of April to June 1983, for the first round of physical examination and questionnaire.

As you will recall, these are the first of the interim reports that go throughout the study and the time periods of -- schedule with the study of three, five, ten, fifteen, and twenty years. This will be the first one, at year one.

All Ranch Hands and controls selected for the study have been sent letters requesting their participation. The first letter went out signed by the Secretary of the Air Force. That occurred October the 16th.

Complete details of the study was followed with a second letter, sent by the Surgeon General of the Air Force. That letter was sent out on November the 6th.

We are now in the process of receiving return receipts of those certified letters. Obviously, there are going to be

some people that we're going to have to go look for, even though we used IRS records to get the initial addresses.

That concludes my remarks, Dr. Shepard, and I'd be pleased to answer any questions.

DR. SHEPARD: Thank you, Phil.

Do the members of the committee have any questions for Major Brown?

Yes, Dave.

DR. ERICKSON: We're anticipating finishing data collection for the questionnaire in the spring, the coming spring. What about dissemination of results?

MAJOR BROWN: That will probably come out at the same time, sir, or probably just a little bit ahead of the physical examination data. It will take a period of time, as you well realize, to analyze all of that.

DR. ERICKSON: One year?

MAJOR BROWN: No. It will actually come out probably in the early part of '82 and that, in essence, becomes one year.

DR. MOSES: '82?

MAJOR BROWN: '83, I'm sorry. Yes, April, in essence, becomes about one year. It may come up--move faster than that, but that's what we've projected as our schedule. We will definitely meet that. If we get some earlier than that, that will be serendipity.

DR. MOSES: I'm curious to know what kind of response you've had already to the October 16th mailing. Do you have a feeling for what the response is going to be?

MAJOR BROWN: Well, we've received a number of letters back, as I indicated, in the sense that they were non-deliverable. So we've got to go look for those people.

We have received some phone calls -- or I have. The Surgeon General has received some letters back. I received one today where the individual said he would be pleased to participate in the study. What that represents is a total --

DR. MOSES: That's not the only one, I hope.

MAJOR BROWN: That's right; we hope that's not the only one. But I really can't answer your question.

DR. SHEPARD: Dr. Murphy.

DR. MURPHY: What was your cohort group, your control group, that you're looking at?

MAJOR BROWN: This was a group of individuals that were in Vietnam -- in Southeast Asia and Vietnam in the same time period, and they were matched for age, race, and duration --

DR. MURPHY: But with no one --

MAJOR BROWN: -- in the job.

DR. MURPHY: But, then, no one without exposure or --

MAJOR BROWN: Very low, low exposure. It's difficult to say if they've had no exposure. They did not fly

any of the Ranch Hand missions.

DR. SHEPARD: Any other questions of Major Brown?

Thank you very much.

MAJOR BROWN: You're welcome.

DR. SHEPARD: Obviously, we're very interested in the Ranch Hand Study because this represents a group of individuals known to have been heavily exposed and in whom the exposure data has been well documented.

We're very happy to have Dr. Frederick Kutz with us this morning, from the Environmental Protection Agency. He will discuss an exposure monitoring program that the EPA has developed.

Dr. Kutz.

EPA EXPOSURE MONITORING PROGRAM

DR. KUTZ: Good morning. I'm pleased to be invited here today to discuss for you some of the chemical exposure monitoring programs in the Office of Pesticides and Toxic Substances of the EPA.

First, I would like to tell you a little about our exposure monitoring philosophy and its scope and then I'd like to talk about some of the recent projects which involve the herbicides and dioxins of direct interest to your group.

Monitoring data at EPA are critical factors in an exposure assessment and, thus, are important elements in the quantitative and qualitative evaluation of risk.

Generally, a qualitative risk assessment is the function of two elements: first, the toxicity of the chemical and, secondly, exposure to that chemical.

Studies in laboratory animals usually are used to indicate actual or potential adverse biological activity, while monitoring data are used to assess the exposure of selected human and environmental components to that chemical.

Data from monitoring activities are also useful to us in determining the environmental pathways through which chemical residues move from their application or usage orbit.

Further, our monitoring studies contribute substantially to our knowledge about the intermediate and final environmental fate of pesticides and other toxic chemicals.

The major orientation of the monitoring programs within the Office of Pesticides and Toxic Substances is toward the assessment of human exposure. Therefore, biological monitoring of human tissues and fluids assumes primary importance. Environmental components, such as air, drinking water, food, and other environmental components which are intimately associated with human life, are considered secondarily. This scheme, we feel, prioritizes our monitoring programs toward the protection of public health.

Current ambient chemical monitoring responsibilities within Pesticides and Toxic Substances include monitoring

soils, raw agricultural crops, estuarine and marine organisms, water, human tissue, and air. Many of these programs are operated in cooperation with other Federal agencies. The National Center for Health Statistics, for example, helps us directly with our human monitoring activities.

Most of these agencies which we cooperate with collect selected specimens for us and then they are forwarded to our laboratories for analysis.

We have a number of various activities in addition to our ambient monitoring that we do. For example, we can use our ambient monitoring to show general population representative levels. In one general population monitoring survey, we have included the capability of detecting residues of the chlorophenoxy herbicides.

This survey, known as the second Health and Nutrition Examination Survey -- and the acronym for that, that we use, is HANES II -- was conducted jointly with the National Center for Health Statistics. That's a component of the Health and Human Resources Department.

This was a four-year study, and throughout this study, members of the general population residing in 67 communities were interviewed and examined in mobile health units. One of the primary objectives of this study was to generate normative baseline data on many biomedical, physiologic, and health parameters. The development of

baseline pesticide residue levels in blood and urine were also among the types of parameters included.

Because of their pharmacodynamic properties, some chlorophenoxy herbicides may be detected in human urine. Included in our chemical analysis of the human urine of the HANES II work were 2,4-D; 2,4,5-T; silvex; and dicamba. Limits of detectability ranged between 5 and 10 parts per billion.

The results of this study showed that no residues of 2,4,5-T, 2,4-D, or silvex were detected in any of the 7,000 or so human urine specimens analyzed. Residues of dicamba were detected in only one percent of the urine specimens analyzed. Considering the use patterns and the human metabolism of these chlorophenoxy herbicides, this is not too surprising.

Please keep in mind, however, that we are still working with this data and that these results are preliminary. They must be statistically weighted before they can be construed as representative of the general population.

For the remainder of my presentation, I would like to discuss three special studies which relate to compounds of interest to your group. The first study involves the use and persistence of 2,4,5-T in rice culture. The second involves the emission of toxic organic matter, including various polychlorinated dioxins from combustion sources. The third

study concerns the detection of 2,3,7,8-Tetrachlorodioxin residues in human adipose tissue from people with no known or occupational exposure to dioxin-containing herbicides.

First of all, the Rice Study. An investigation of 2,4,5-T residues in rice was initiated by our branch in 1979. Forty-two paired samples of soil and rice were collected in rice-growing areas of Arkansas and Louisiana where 2,4,5-T was applied for weed control. Samples were collected from rice fields which had received 2,4,5-T applications during the 1979 growing season. The 2,4,5-T was applied early in the growing season after crop emergence -- generally in late April, May, or early June. The soil and rice crop samples were collected in mid-September, 1979, after the fields had been drained, but before harvesting.

If we could have the first viewgraph, please.

(Showing of viewgraph.)

I've tried to give you a myriad of summary statistics here.

As shown on this slide, 57 percent of the 42 rice samples contained detectable residues of 2,4,5-T, ranging from 1.1 to 13 parts per billion, with a limit of detection equal to about 1 part per billion.

Results of the rice analyses are shown in the next slide.

(Change of viewgraphs.)

Concentrations of 2,4,5-T in Rice Growing Soils from Arkansas and Louisiana
(residues expressed in parts per billion)

LOCATIONS	Total No. Sites	Percent of Positive Detections	Maximum Value Detected	Median	Estimated Geometric Mean	Positive Arithmetic Mean
ALL SITES	42	57.1	13.	1.5	0.3	4.9
ARKANSAS	28	53.6	13.	1.6	0.3	6.4
LOUISIANA	14	64.3	6.3	1.4	0.3	2.5

Concentrations of 2,4,5-T in Rice Grain from Arkansas and Louisiana
(residues expressed in parts per billion)

LOCATIONS	Total No. Sites	Percent of Positive Detections	Maximum Value Detected	Median	Estimated Geometric Mean	Positive Arithmetic Mean
ALL SITES	42	67	227.	17.2	2.4	58.9
ARKANSAS	28	54	109.	5.3	0.7	40.9
LOUISIANA	14	93	227.	47.9	30.3	79.7

For the rice, 67 percent of the 42 samples analyzed contained detectable residues of 2,4,5-T, ranging from 3 to 227 parts per billion. The limit of detection in rice was 3 parts per billion.

The results of this study are quite different from earlier studies in which rice and soils were analyzed for 2,4,5-T residues. The Dow Chemical Company conducted several studies which examined rough rice and soils as well as commercial rice. These studies showed no detectable residues of 2,4,5-T at detection limits of approximately 10 parts per billion.

Thank you. You can turn the slide off momentarily now, please.

The main difference between this study and previous studies is that this study used chemical methodologies with lower detection limits than previously used methods. Previous studies, which employed chemical methodologies developed about 1970, generally had minimal detection limits of 10 parts per billion. The detection limit in this study was 1 part per billion for soil and 3 parts per billion for rice samples. Ninety-two percent of the 24 positive detections in the soil samples were below 10 parts per billion and 11 percent of the 28 positive detections in the rice samples were below 10 parts per billion.

The chemical methods used in this study were

essentially modifications of those developed in our laboratory at the Toxicant Analysis Center in Bay St. Louis, Mississippi, directed toward the National Surface Water Monitoring Program. That indicates that they were detected by electron caps or gas chromatography.

In addition, most of the positive results have been confirmed by combined gas chromatography and mass spectrometry. This provides additional assurance that the detections are, in fact, 2,4,5-T. None of the samples, however, have been analyzed for dioxins.

It should be emphasized that the scientific meaning of these new residue findings has not been defined. As most of you know, past EPA regulatory efforts on 2,4,5-T and silvex were prompted, in large part, by the dioxin contamination of these two herbicides.

Additionally, these results do not contribute to our understanding of the environmental movement of dioxins, since we believe that the pathways of 2,4,5-T and TCDD may be dissimilar.

I'd like to spend awhile telling you a little about our Combustion Study. Because of the growing concern for the possibility of human exposure to toxic substances as a result of combustion, a study to provide statistically valid estimates of the levels of organic emissions from combustion sources was begun.

Among the main categories of concern are coal and refuse-derived fuel combustion and residential wood combustion. The compounds of interest are included in a broad category, known chemically as "Polycyclic Organic Matter." These include polychlorinated biphenyls, polychlorinated dioxins, polychlorinated furans, phenols, and other polynuclear aromatic hydrocarbons and other organic compounds. We do a very wide range of scans on our emissions samples.

In order to make a statistically valid estimate of national emissions, it is important to have information on emissions variability within any one facility. Therefore, a pilot study at two facilities was conducted in order to describe emissions variability. This variability was used to design the national study, which is ongoing right now.

One of the facilities sampled in the pilot burned 85 percent coal and 15 percent refuse-derived fuel, whereas the other burned raw municipal refuse. These facilities were sampled for nine and ten days, respectively, and samples of fuel, ambient air, water, bottom ash, fly ash, and flue gas were taken.

Using the total organochlorine variability in the results between days at each facility and between the two facilities, we statistically estimated that the most cost effective method to achieve a precision of about plus or minus 50 percent on our national estimates was to sample seven

coal-fired power plants and nine incinerators for five days each and analyze these samples according to a tiered analytical procedure where "positives" from one tier went onto the next. The ultimate analysis for dioxins and furans was performed by combined gas chromatography-high resolution mass spectrometry.

Four coal plants were sampled in 1981 as part of the national program, and the analytical results are expected next month. The remaining three coal plants will be sampled in the coming months, while at the same time we will begin designing a sampling strategy for residential wood combustion. The national emission estimates for the coal-fired power industry will be available late next year.

For those of you interested in the polychlorinated dioxins and the polychlorinated furan results from the pilot study -- and if we could have the third slide, please (showing of viewgraph) -- no dioxins or furans were detected in any medium in the coal and refuse-derived fuel facility at a detection limit of a half nanogram per gram in ashes and .25 nanograms per cubic meter in the flue gas. Only the flue gas at the municipal waste combustion facility contained detectable quantities of these compounds.

You can see, particularly, the furan and the dioxin data in the next slide.

(Change of viewgraphs.)

SLIDE 3

Highlights of Combustion Study (Pilot)

Emissions from a Small Coal Burning Power Plant with 15% Auxiliary Refuse Burned

Substance	Emission Rate (g/yr)
Total phenols	19,000
Naphthalene	1,200
Phenanthrene	800
Pyrene	400
Fluoranthene	200
Benzo(a)pyrene	20
PCBs	50
PCDDs and PCDFs	None Detected

Emissions from a Large Municipal Incinerator

Substance	Emission Rate (g/yr)
Total phenols	2,700
Trichlorobenzenes	500
Phenanthrene	200
Fluoranthrene	40
PCBs	20
Total PCDDs	30
Total PCDFs	350

Residues of Dioxins and Furans Observed in Flue Gas of a Muncipal Waste Combustion Facility[1]

Isomer Groups	Mean[2] Concentrations (ng/cubic m)	Mean[2] Quantities Emitted (ug/hr)
Tri - CDD	13	1100
CDF	300	26,000
Tetra - CDD	6.3	540
2,3,7,8-TCDD	0.4	34
- CDF	90	7600
Hexa - CDD	16	1400
- CDF	62	5200
Hepta - CDD	7.6	640
- CDF	7.5	640
Octa - CDD	2.5	220
- CDF	0.6	52

[1] not corrected for recoveries
[2] mean of 3 data points

As you can see, we uncovered a wide variety of furans and dioxins, including 2,3,7,8.

DR. MURPHY: Is that unit micrograms per hour?

DR. KUTZ: Yes. The first column is the concentration of the emission in nanograms per cubic meter. I didn't make the typical scientific expression for "cubic meter" because of the footnotes. I thought that would be confusing.

The second column is actually the emissions per hour. And that, of course, considers the emission rate of the combustion facility.

Thank you for the slide.

I'd like to turn now to our very limited investigations of 2,3,7,8-TCDD in human adipose tissue.

Several investigators have indicated that minute quantities of TCDD are present (in low parts per trillion range) in specimens of adipose tissue collected from members of the general population.

We also have conducted a very limited number of analyses of this type. As control specimens for some of the analytical programs done by the EPA Dioxin Monitoring Program in early 1980, six specimens of human adipose tissue were collected from residents of an urban Ohio county. These specimens were excised during post-mortem examinations and they contained almost a pound of adipose tissue and were from individuals who, at least, according to the medical record, had

no recorded or known exposure to silvex or 2,4,5-T.

Subsequently, they were analyzed in duplicate-- some of them were analyzed more than in duplicate -- following the EPA Dioxin Monitoring Program protocol. The instrumental determinations were accomplished at two independent laboratories.

The results demonstrated that all specimens contained residues of 2,3,7,8-TCDD. Levels ranged between 5 and 12 parts per trillion, with a detection limit below 5 parts per trillion.

It should be emphasized that all the studies that we have seen conducted to date, including this one, have been accomplished using small sample sizes and deliberate specimen collection criteria. Consequently, these data cannot be construed as being representative of anything except those individuals from which the tissues were taken and, particularly, not of the general population.

DR. MURPHY: What were those concentrations again --

DR. KUTZ: They ranged between 5 and 12 parts per trillion.

DR. MURPHY: Five being the detection limit?

DR. KUTZ: With a detection limit slightly below 5 parts per trillion.

I hope I've shown you some of our capabilities today and talked about some of the data that would be of interest

to you. To point out or to focus my talk, I think the Combustion Study has relevance here because of its detection of the emission of TCDD. The 2,4,5-T data from our Rice Study indicates that -- or, let's say, contra-indicates what we have always thought about 2,4,5-T in that it is a fairly non-persistent pesticide; that this data at least indicates that applications can last up to five or six months in the rice and in the soil.

Our human adipose tissue sampling, although not representative -- and I have to emphasize that -- I believe does indicate that if we are going to be looking at an exposure situation of veterans exposed to Agent Orange, some consideration has to be given to the determination of whether or not 2,3,7,8-TCDD is a ubiquitous contaminant of human tissue.

Thank you.

DR. SHEPARD: Thank you very much, Dr. Kutz. We really appreciate that very comprehensive review. I hope we can have a copy of that so that we may circulate it to members of the committee so they can review it in more detail.

DR. KUTZ: Yes. And to help your stenographer out, I'll -- I don't want to give you this. This is the large type. But in my office I have a copy, and I will send it to you.

DR. SHEPARD: And if we could have copies of your --

DR. KUTZ: You will, yes.

DR. SHEPARD: -- viewgraphs and so forth, that would be very helpful.

Are there any questions to Dr. Kutz?

Yes, Dr. Moses.

DR. MOSES: I wanted to know what plans EPA has to do --in view of these findings, of these people in Ohio, what plans you have to monitor human tissue for TCDD, specifically adipose tissue. Are there any plans for that now?

DR. KUTZ: I'm unaware of any plans, at the moment, to do that.

DR. SHEPARD: Yes, Dr. Kearney.

DR. KEARNEY: Just to comment, this suggests to me that we're going to have to be very careful now, in looking at adipose tissue samples, to draw any conclusions as to source. I know that a number of the states are beginning to consider looking at adipose tissue in veterans in Vietnam. I think we need to, perhaps, be a little careful as to our interpretation of that as cause and effect because it suggests now that there are other sources. We have the agricultural experience, the emission experience, and the Vietnam experience. It may be very difficult now to make any sense out of this.

DR. SHEPARD: I would like to ask Dr. Kutz, if I may, what plans -- and maybe you've mentioned it and I missed it. But are there plans for ongoing tissue analyses or fat analyses

beyond this point, and is there going to be any attempt to do any clinical correlation, if these are autopsy materials, any clinical correlation between the health of the individual and the presence of these TCDD's in the fat?

DR. KUTZ: We don't have any plans to that effect right now. We have had discussions with some other agencies that may be interested in continuing this work.

I must say that we do have a laboratory facility in Bay St. Louis, Mississippi, that has the capability, a tremendous capability for dioxin analysis. We believe that this laboratory -- at least, I believe that this laboratory has very updated health and safety conditions that would allow for the safe analysis of dioxin specimens.

We have a containment suite in which we perform the extractions, and right now we are trying to bring our high resolution mass spec on line to do dioxin and instrumental determinations.

So I'm hopeful that perhaps, through interagency cooperation, we can find a way of continuing some of this work.

DR. SHEPARD: Thank you.

Yes, Dr. Murphy.

DR. MURPHY: On your laboratory in Mississippi, did they do the adipose tissue analyses as well as the residue analyses? They're set up to do all that?

DR. KUTZ: In the results that I have spoken of

today, they did the entire 2,4,5-T determinations that I talked about. In the adipose tissue, they did the extractions and the instrumental analyses were done, I think, at Wright State and at the Health Effects Research Laboratory in North Carolina, the EPA Health Effects Research Laboratory in North Carolina.

The combustion results are being done under contract. Although some of the extractions were done in Mississippi, the majority of the work was done by our contractor, Midwest Research Institute, at their facility, as well as at some subcontractor facilities. We have such a huge --

DR. MURPHY: Well, the Mississippi laboratory is really sort of a coordinating lab. It's not an analytical lab.

DR. KUTZ: No, it is an analytical laboratory --

DR. MURPHY: But not for the dioxins.

DR. KUTZ: No, not for the EPA Dioxin Monitoring Program, no. It was the extraction laboratory.

I can't really report to you, with any kind of authority, the exact status of the EPA Dioxin Monitoring Program simply because I'm not really involved with it. By administrative order, that was moved to the Office of Research and Development several months ago and I'm not privy right now to its exact status.

DR. MURPHY: Maybe this will be outside of your area

of information, then. But I was going to ask, do you have any similar comparisons with the couple of facilities that have been authorized to combust polychlorinated biphenals as related materials to that exclusively -- well, I don't know exclusively, but they are authorized to do this. You know, there are relatively few of those in the country, one of them being a neighbor.

DR. KUTZ: Yes. I'd sort of like to throw that question to Dave Redford, who is a colleague of mine. Maybe Dave could answer your question.

DR. SHEPARD: Dave, could you come up here, please, and use the microphone? We'd like to get this on the record.

This is Mr. David Redford, also from the Environmental Protection Agency.

We're happy to have you here, Dave.

MR. REDFORD: The data from the PCB burns that you're speaking of is public right now, and I haven't really compared it to our results yet. It's not as detailed as our results. Is that what you were referring to?

DR. MURPHY: You say it is public, it's published? Is that --

MR. REDFORD: It's in the contractor reports and --

DR. MURPHY: I see.

MR. REDFORD: -- I believe they're in the public domain right now, yes. If you would like --

DR. MURPHY: Do you have any sense of the quantitative relationships, in terms of dioxin emissions or --

MR. REDFORD: No, I don't, to be honest with you. No. I'm not sure. I haven't really had a lot to do with those burns. I believe they are reasonably comparable. They are all very low, but I'm not sure what they are.

DR. KUTZ: Barclay, I'd be pleased to provide that data, if it is published, to you. Then you could distribute it to those of interest.

DR. SHEPARD: Yes, right. I'd be happy to receive that. Thank you.

Dr. FitzGerald, do you have a question?

DR. FITZGERALD: Please.

In your combustion emission studies, has there been any evaluation of the refuse and the content of the refuse before combustion?

MR. REDFORD: I'd like to answer that.

There were two different facilities that we looked at. In the one that burnt raw refuse, you have to imagine a garbage truck coming up and dumping in the raw refuse containing refrigerators and tires. In an attempt to get a handle on how it varied, we used total organic chlorine, which Dr. Kutz referred to before. In using that, we saw the variability in there was no tremendous that if we had analyzed each one of those samples, whatever data we got from it would

have been virtually meaningless.

We didn't look at that refuse, but we did not look at the RDF in the other facility. We analyzed it, and we do have data on what was in it. I don't believe we detected any dioxins in there. But I do have a list of what we did find in that RDF.

DR. KUTZ: So, therefore, your conclusion would be that the dioxin that you did find, subsequently, was a result of the combustion?

MR. REDFORD: No, because we did not find any dioxin in the facility where we did analyze the refuse. That was at the coal/RDF facility. We did not detect any dioxin there ---

DR. MOSES: No, that was the waste treatment --

MR. REDFORD: Right. We did two facilities. One burnt coal and RDF and we didn't find anything there, and one burnt just raw refuse and that was where we did detect it. We could not look at the raw refuse itself.

DR. SHEPARD: Did you make any correlation between the temperature and the presence of dioxin?

MR. REDFORD: We have not statistically looked at all those factors yet, no.

DR. SHEPARD: But that would make a difference, right? If it were at a higher temperature, you would likely pick up less TCDD --

MR. REDFORD: I would believe so, yes. I believe it would affect it somehow, yes.

DR. SHEPARD: Yes, Dr. Kearney.

DR. KEARNEY: Just to comment, Dr. FitzGerald asked a very probing question here. It's a rather interesting question. You know, I think we're all concerned about the source here. TCDD is a paralysis product, classically. That's how it was found. Is it arising from some other correlated compound as a precursor in the system? I think that's a very interesting question.

I know we don't want to get into the garbage business but, by the same token, it might be rather informative to find out what the source of this is. I think that's our next great challenge, and it's a very interesting question.

DR. SHEPARD: Yes, Dr. Murphy.

DR. MURPHY: On your residue of soil in your Rice Study, you had 3 to 300 parts per billion in soil, as I recall, in September. Do you know what the residue was, say two --

DR. KUTZ: Immediately after --

DR. MURPHY: -- weeks afterward?

DR. KUTZ: No.

DR. MURPHY: I mean, can you get any idea of the half-life, what's really happening in --

DR. KUTZ: No, we really don't have any information.

This was a one-visit-to-a-field study, and we don't really know what the residues were other than having the owner of the land or the manager of the land say it was treated with 2,4,5-T in the spring.

DR. SHEPARD: Thank you very much, Dr. Kutz and Mr. Redford. I think we'd better move along. I appreciate your comments and your contributions. It's very interesting. We'll be looking forward to hearing more about the program.

I'd like now to call on Major Alvin Young, from the Air Force. Major Young has been on loan to us from the Air Force for the past few months, and we're most delighted to have him as a member of our team. He will make a brief report on the recently held International Dioxin Symposium.

INTERNATIONAL DIOXIN SYMPOSIUM 1981 & 1982

MAJOR YOUNG: Thank you, Dr. Shepard. I'll make it very brief.

Part of the function of our effort here, of course, is to exchange information and to bring new information to your attention, and Dr. Kutz certainly did that on some of those areas.

There was a 1980 symposium on dioxins. It was held in Rome last October. We have just received an announcement that the publication of those proceedings are available. I'll try to get this into the minutes of it, and if any of you are interested in ordering a copy of that, a very expensive

$75 per book, at least the proceedings are available.

As all of you know, we have recently completed an international symposium on dioxins. Actually, it was the second annual meeting here on the subject, and it was held in Arlington, Virginia, the 25th through the 29th of October, this year.

There were 250 registered participants, and a lot of people were there that were not registered. Fifty international individuals were there, representing about ten different countries.

In addition to that, there were 50 of our environmental physicians from the VA and some of our VA researchers, which I really think speaks highly of the interest that the VA had in that particular conference.

There were sessions in Animal Toxicology, Human Observations, Environmental Chemistry, Environmental Toxicology, Biochemistry Metabolism, and Laboratory Safety.

In addition, there were Blue-Panel meetings that met every evening on each of those topics. It talked about what was the current status of information, what did some of the information that we were just picking up during the symposium mean in terms of present science, and what were the ongoing studies.

Now, we've asked for all the Blue-Ribbon Panel reports to be submitted down to us so that we can circulate

them to interested people.

There is a publication coming out by Enviro Control that's a list of the abstracts and the participants. We'll attach the Blue-Ribbon Panel summaries to those and make them available to all the members of the committee.

There were manuscripts prepared at this last symposium. Those manuscripts have been submitted to Enviro Control because they're the coordinators of the conference. They have made an arrangement with Plenum Press to publish all those manuscripts. We've been assured by Plenum Press that within a hundred days of receipt of those manuscripts, there will be a publication available.

There already are plans for some 1982 conferences on dioxins. That certainly tells you the level of interest in this particular area. The American Chemical Society has announced a symposium on chlorinated dioxins and dibenzo furans for the 12th through the 17th of September, in Kansas City, Missouri. The third international symposium on dioxins is now scheduled for late October, in Salzburg, Austria.

So, 1982 holds out all sorts of opportunities to attend symposiums related to this topic of dioxins.

That's it in a nutshell.

DR. SHEPARD: Thank you.

Are there any questions for Dr. Young?

Yes.

DR. MURPHY: What was new?

MAJOR YOUNG: You know, I think some of the observations on where the dibenzo furans and the dibenzo dioxins were being found in the environment was the newest information. Some of the standards that are being set -- for example, the Canadians have set a standard of 25 parts per trillion of TCDD, the 2,3,7,8 isomer, in food, food products. Our FDA is proposing a standard of 50 parts per trillion of the 2,3,7,8-TCDD isomer in fish.

Discussions about those monitoring results and techniques really was the new area. There were some intense presentations on human observations but, as most of you know, the problem is that studies that are ongoing are not going to be reported back until late '82 or '83. So the protocols were discussed. Some tentative kind of observations were made.

For example, the Human Observations group were very concerned on what other things do you monitor in individuals that have been exposed to dioxins besides chloracne. And we tried to get a consensus.

A question from many of our VA physicians to the researchers and to the scientists giving the papers was: "What do we look for in a physical exam of someone that has claimed exposure to TCDD? What should we be looking for?"

There was a lot of disagreement among the scientists.

The consensus was that only chloracne is an identifiable condition. If an individual has been exposed to TCDD and they have chloracne, super, you know. I mean, you can tell that they've been exposed. But what else can you tell?

Well, the data are inconsistent on liver, on other body functions, body chemistries, just inconsistent.

DR. MURPHY: Well, does this controversy center around specificity, then, rather than the occurrence? I mean, even chloracne is not --

MAJOR YOUNG: Not only caused by 2,3,7,8, that's right. That's right.

DR. MURPHY: It may be very characteristic.

MAJOR YOUNG: Obviously, we asked the chemists to address the issue of the patterns of chemicals being found as one method of detecting what the source might have been for that exposure.

There's a lot to be done. I think that is probably what came out of this symposium. We just, frankly, do not have a good handle on sources.

DR. MURPHY: Was there anything new or significant out of the Seveso follow-up?

MAJOR YOUNG: I think the thing that was new to us was the lack of --

DR. MURPHY: That's not new.

MAJOR YOUNG: Well, they did give a summary and they went through the birth defects, and so on, and the lack of those things that were detected or associated with exposure. The only thing they concluded was that chloracne was all that was seen. No indications of increased birth defects, no indications of liver problems, no indications of neuro --

DR. MURPHY: There haven't --

DR. SHEPARD: No documented cases yet?

MAJOR YOUNG: No documented cases.

DR. SHEPARD: They're still looking?

MAJOR YOUNG: Yes.

The interesting thing was that they've come to the conclusion that, "Gee, chloracne we found. We didn't find a lot of other things."

DR. MURPHY: What about the immunological? Was anybody looking at that?

MAJOR YOUNG: Yes, there was. Again, the lack of findings, of positive findings--the findings were negative.

DR. MURPHY: Was that Seveso people or --

MAJOR YOUNG: The Seveso. The five-year study on the Seveso folks was presented.

DR. SHEPARD: Some of it. I don't want anybody to get the impression that we've heard the last word on Seveso.

MAJOR YOUNG: No, we haven't.

DR. SHEPARD: There's a lot more going on.

Unfortunately, some of the investigators who were doing the Seveso work were not able to come to the conference, so I suspect there is a lot of data out there that we have not yet heard.

We are also anxiously awaiting more detailed reports on industrial exposures in this country. We still have not heard from a number of investigators who are looking at chemical plant accidents or the results from industrial workers, so we're in hopes that that information will gradually come in.

We know there's some data out there that has not yet been reported.

MAJOR YOUNG: The Blue-Ribbon Panel summaries will be of greatest value because they assess what we know and where we stand on those issues.

DR. MURPHY: They will be made available to the committee?

MAJOR YOUNG: Yes. We've already asked for them. They should be here within the next few days, and we'll try to get them out to you.

DR. SHEPARD: Any other questions?

Dr. Irey.

DR. IREY: There are ten or a dozen industrial occupational --

DR. SHEPARD: Oh, excuse me. I'm sorry. Would you grab a microphone, Dr. Irey? Thank you.

DR. IREY: There are ten or a dozen industrial occupational incidents and accidents that have happened over the last 20, 30 years. The largest single one that I know of is Seveso, where 700 people, I think, were involved. The next was 200 or so at Nitro, West Virginia. Now, has there been any follow-up? That was, I think, in the 40's or 50's.

DR. MURPHY: '49.

DR. IREY: Has there been any follow-up as cohorts? These are cohort-type studies where the common denominator is evident exposure or possible exposure to TCDD. Has there been at this conference any follow-up of such a long-term experience where your latent period for carcinogenicity is perhaps pretty well satisfied, three decades? Is there any follow-up on that?

MAJOR YOUNG: Dr. Gaffey was there.

DR. SHEPARD: There was some, Dr. Irey. Dr. Gaffey, from Dow Chemical, was there.

DR. MOSES: No, Gaffey is from Monsanto.

DR. SHEPARD: I'm sorry, Monsanto.

Perhaps Dr. Moses would like to address that question. We had hoped that she could be there, but other duties prevented her from being there.

DR. MOSES: As you know, Dr. Suskind, who is also on

this committee, has studied the workers. A mortality study has been reported from Monsanto, about two years ago, I guess, now. It was last January. And I won't go into what was found. Dr. Suskind has done a morbidity -- been involved in a morbidity study of these workers and I was formerly at Mt. Sinai in New York. We will, I hope within a month or so -- I'm just waiting for all the other comments to come in. We will be publishing a paper on a study that we did of workers at this Nitro facility.

We also, it might be of interest to the group here, are doing some immunological studies further. We have not completed those. Those still have to be done. And, also, we are doing some studies on perforans in the urine, as recommended at the Rome meeting, which I also attended.

So there are things in the pipeline, as Barclay stated. I think, by certainly this time next year or certainly by the next meeting, we're going to have a lot more data and probably already, I hope, in published form by that time, and I assume Dr. Suskind as well. I don't know. I can't speak for him.

MAJOR YOUNG: Certainly, that was the outcome of this symposium, that there is a lot of information in the pipeline and we should be hearing soon from many of the various scientists, worldwide, on their findings.

DR. MOSES: Could I just make one more comment?

Interestingly enough, one other thing that we're doing that the group might be interested in -- we're very interested in it. We have also done some skin biopsies of workers at that plant, some of whom had chloracne and some who did not, all of whom had exposure to 2,4,5-T in the production process. Dr. Crow, who was also at this meeting, is involved in our study of this. So that is something else that will be, hopefully, reported out earlier next year.

DR. SHEPARD: Dr. Erickson, did you have a question?

DR. ERICKSON: Yes. I was at the dioxin meeting but was unable to stay for the last day and I didn't hear the Blue-Ribbon Panel presentation, so I wonder if you might tell me what the Human Observations Panel came up with in regard to soft tissue sarcomas.

DR. SHEPARD: If I may answer that question -- I was there, of course, as was Al. I think that it still remains in the area of concern. I don't think anybody is prepared to state categorically that they believe that there is a direct cause-and-effect relationship between exposure to 2,4,5-T or TCDD and the appearance of these soft tissue sarcomas.

As you all know, the Swedish study suggested that there is an increased incidence of this group of tumors in workers with herbicides. A number of individual reports have been submitted, many of them in the form of letters, to Lancet, suggesting that these tumors are appearing among peopl

known to have been exposed.

The plea I would have is that the term "soft tissue sarcoma," as it's being used, tends to suggest that this is a tumor or a closely related group of tumors, and nothing could be further from the truth. I think Dr. Irey would agree, and Dr. Lingeman, that this is kind of a -- I hate to use the word "wastebasket," but it's a collection of convenience or a term of convenience which refers to a number of very divergent types of tumors which individually are rare, which do not, I don't think, in any pathologist's or any epidemiologist's view, have a common etiology. I just want to point that out. But there is, obviously, a growing interest in the possible relationship of soft tissue sarcomas and these herbicides.

Dr. Cordle.

DR. CORDLE: One slight correction. The FDA has not proposed a 50 part per trillion tolerance for TCDD. What we have done is issue a public health advisory to the eight states which border the Great Lakes, where there is a great deal of sports fishing, as you know, indicating that there should be some caution in consuming fish with residues between 25 and 50 parts per trillion.

What we're doing -- you see, this is intrastate commerce in this fishing situation, so we really don't have control over it, so that our only alternative is to issue a public health advisory to the state officials, Public Health,

and the governors, which we have done.

The Canadians have, of course, instituted a 25 part per trillion for TCDD in that they close their fishing areas when they reach those levels in a certain number of samples of fish. But they close the fishing grounds, not enforcing it through the distribution of fish, as such.

MAJOR YOUNG: Thank you for that clarification. That did not come across at the meeting at all. It came across as a standard rather than as a --

DR. CORDLE: Well, we've had considerable discussions, of course, with the Canadians and these actions are the result of a joint U.S.-Canadian task force which met for the period of a year.

MAJOR YOUNG: It's good to have a clarification of that.

DR. MOSES: Could I just ask Dr. Young one more question?

DR. SHEPARD: Sure.

DR. MOSES: I'm curious, now, if anything came up about 2,4-D and the dioxin contaminants in 2,4-D. That was quite a highlight of the meeting the year before. Has there been any more work than what has already been reported on that, that you know about?

MAJOR YOUNG: No. Nothing came up on that as an official paper. There were some out-in-the-hall kind of discussions

on it, but nothing officially released at all.

DR. SHEPARD: I think we'll take a five-minute break and then reassemble to hear Dr. Irey's report.

(A brief recess was taken.)

DR. SHEPARD: If we could come to order, please.

We're very happy to have with us this morning Dr. Nelson Irey, from the Armed Forces Institute of Pathology, who will give us an update on the AFIP Agent Orange Registry.

Dr. Irey.

AFIP AGENT ORANGE REGISTRY

DR. IREY: Thank you, Dr. Shepard.

Three years ago at the AFIP, a registry was set up to answer the question of what diseases men with service in Vietnam were suffering from, as reflected in biopsy material removed at surgery and in autopsy material.

This was three years ago.

This is a report, a summarization of the findings of this biopsy and autopsy material, in 408 cases. Actually, we've got about 600 now in the registry. Two-thirds of our cases have come in since the first of the year, so there has been an exponential increase in the number of cases recently.

Dr. Lingeman and Dr. Mullick and I have been sharing the morphologic diagnostic work. At the Institute, as you may know, there are about 40 anatomically-oriented departments and

registries, and we almost routinely use the consultative facilities that these other areas offer. So it's not just Dr. Lingeman's and Mullick's and my impression diagnostically. We have fairly good backup on these diagnoses.

This study has certain limitations. We're not addressing the problems of teratogenicity, mutagenicity, decrease in fertility, or neurobehavioural problems.

We do have the capacity, I think, to find in these studies several things: one, the residuals that might be present in Vietnam veterans, of acute toxicity, from which they have recovered; and chronic toxicity residuals, if they were exposed over a year or more while in Vietnam.

Well, let's go on to the first slide, to find out what the medical problems of Vietnam veterans are now.

Can you give me the next?

Now, we're looking in this series for three things, features of unusuality: either peaks or clusters occurring in organ-diagnosis combinations; or pathologic changes that are unusual for a particular site of organ; or unusual ages for a particular process, particularly in tumors.

This is on the ground that in environmental chemical

diseases, generally a particular chemical will have a particular target or a limited number of target organs, so that if you see enough cases, there should be reflected increases in incidence relating to the chemical if it is being responsible for disease.

A little demographic data. Here's our distribution by age. You notice the peak is in the 30-to-39-year group, and then there's an even drop, if you graph this out, from then on.

If you dropped this back in time ten years, you would have a dominance of the 20-to-29 group. From the point of view of age distribution, this seems to be a fairly even curve and it would be expected to be something like this because of the dominance of the very young group in our Armed Forces in Vietnam.

It's interesting that although we have 142 unknowns as far as race, 222 were white and only 39 black.

Males, of course, dominated.

Source of cases. The VA hospitals dominated with 345. The Air Force and the Army and Navy also joined us, in asking us to serve as a pathologic center for the study of cases in Vietnam that are still on active duty.

We have material from 45 states, so it's a fairly wide geographic distribution.

Now, the next ones are a tabulation of the site or organ of this biopsy and autopsy material. By the way, the majority of our cases were biopsies or surgical specimens.

Skin and subcutaneous tissues, dominated. Then lymph nodes, liver, and lungs followed. These are in order of frequency.

I show you these, slides on site frequency to give you an impression of the wide distribution anatomically of this material. I won't go into recitation of the various organs and viscera and sites.

We made a special tabulation of the liver because the liver is one of the sites that, in acute toxicity studies in accidents relating to TCDD, there have been liver changes; necrosis, and fatty metamorphosis, So we were looking particularly for any evidence of liver damage residuals.

Metastatic carcinoma leads the list with seven, then fatty metamorphosis.

There's nothing too striking here, in the way of significant peaks. There are 31 cases in this liver

tabulation and 11 of the 31, in the record, have either a history of chronic alcoholism, drug abuse, or both, so that this further complicates the issue of determining the cause for these morphologic changes in the liver.

DR. GROSS: Excuse me, Dr. Irey.

DR. IREY: Yes, sir.

DR. GROSS: These diagnoses, are they single diagnoses? You could have multiple diagnoses for --

DR. IREY: These are generally, let's say -- fatty metamorphosis and focal necrosis are made together in the same case.

DR. MURPHY: You listed 17 cases for liver samples but you mentioned this was drawn from a sample of 31.

DR. IREY: No. There are 31 liver cases on these series of diagnosis tabulations, 31 cases, 11 of which were either chronic-alcoholic, drug-abuse, or both.

DR. MURPHY: Okay.

DR. IREY: Did I answer your question, Adrian?

DR. GROSS: What happens in the case of several diagnoses for the liver, let's say?

DR. IREY: Yes. Well, we have an answer at the top. The first two there had a combination of fatty metamorphosis and focal fibrosis, one case, and then one with portal fibrosis.

Actually, covering necroinflammatory disease with early cirrhosis would have a number of diagnoses on the

diagnosis sheet.

DR. SHEPARD: Excuse me, Nelson. I think the question is, are the numbers on the right-hand column cases or diagnoses?

DR. IREY: They're diagnoses that are made.

DR. SHEPARD: So there may be more than one diagnosis per case?

DR. IREY: Right.

DR. MURPHY: So we're talking about seven cases of metastatic carcinoma out of 17 examined, seven out of 17?

DR. IREY: There were 31 liver diagnoses made, of which seven are metastatic carcinoma.

DR. MOSES: And there were 17 liver specimens, of course, right?

DR. IREY: Yes.

Now, the benign tumors are listed here. Lipoma leads the list, and dermatofibroma next. Angiolipoma could be included with the lipomas. Then there's a broad scatter pattern of polyps, with a wide distribution.

It's interesting that the lipoma is a peak, is a cluster, as is the epidermal inclusion cyst, as you'll see in the Skin Diagnoses. Now, this might be explained on the basis that both epidermal inclusion cysts and lipomas

are subcutaneous, just beneath the skin, are palpable and visible to the patient, and prompts him-- with his interest and concern about tumors, to go for medical attention and biopsies more than, let's say, you or I, who may be carrying a fatty tumor for years and say, "Well, don't bother with it." So this is one peak, lipoma.

Here's a scatter pattern of the adenomas and papillomas occurring in one or two at a time.

It's interesting that we had three cases of both angiolipoma and lipoma.

Benign tumors continued in single instances are as listed here, with no tendency to peak or to have clustering.

Malignant tumors in lymph nodes led the list, and lungs second. Hodgkin's Disease and malignant lymphoma -- actually there are three or four subgroups in these major categories and there was a broad, single or two-case distribution in the breakdown of subsets of Hodgkin's and malignant lymphoma.

On the lung there were eight cases, but they broke down in specific histologic types, as you see here.

Further on malignant tumors, there were eight skin malignancies. Basal cell carcinomas -- now I don't have it here, but I've looked into those specifically, as far as their

ages and their sites. Their ages are within the usual expentancy and their sites are either head, neck, or trunk, which are usual sites.

The gastrointestinal tract was the seat of five tumors, as broken down here.

Further on malignant tumors, the testis was the seat of three tumors, two of them with mixed or double tumors, as listed here. There was one chondrosarcoma, and one multiple myeloma.

This continues, then, the malignant tumors with either two or one, as listed here: prostatic carcinoma, two, and so on. There is no peaking here in this.

Now, there were six cases in the malignant group that had unusual features, such as the colon, adenocarcinoma. It was an unusual type of mucinous cancer.

There was one jejunal cancer.

It's unusual to have a cancer of the jejunum, and the age was young, 37.

The lung had one case that was age 31, which is an unusually young age for that tumor.

There was a double tumor in one case. The man had both an anaplastic adenocarcinoma of the lung and a prostatic CA. They were different histologic types and showed up metachronously.

Then we had one very young prostatic cancer, at the

age of 44. Usually, they're in the 50's or above.

The testis, a combination of a gonadoblastoma, a sarcoma of the epididymis, and an inguinal node, being the seat of metastatic cancer. This is a most unusual case but, again, a single instance.

Now, the Diagnoses on Remaining Cases. We listed the liver and malignant and benign tumors specifically because of pastexperimental experience and with previous episodes or accidents in the dioxin area. Now, this is a general, alphabetized and numerical combination of the findings, and I'll go through these rather rapidly because there's a long list. But you can get an idea of the broad spread of diagnoses made in these 408 cases, most of these single instances.

There were two overdose cases and one gunshot suicide in this list.

Now, the broad anatomic location of the lesions removed and the broad diagnostic spread, I think, speaks for a fairly representative submission of material.

The one common denominator that we asked pathologists to use in sending us material is one criterion--service in Vietnam--no selection otherwise because that would skew the findings.

We don't know how they are adhering to this, of course. The VA has some 170 or 80 hospitals scattered over the country, and it's impossible to monitor the adherence to this directive. But at least we're trying to get material, whether it's a shrapnel material, as you see here, or a varicocele, or scar tissue.

Many of these have no chance of being related to dioxin exposure, such as a hernial sac or a torn meniscus from a football injury, and so on. But I think they reflect the fact that at least, in many instances, they are not selecting just tumors or just this or that in their submission of material.

DR. MOSES: Dr. Irey --

DR. IREY: Yes.

DR. MOSES: What about these people, 80 to 89 or 70 to 79? They served in Vietnam, too?

DR. IREY: Well, if you put it back, say, 20 years, the earlier ones --

DR. MOSES: It would be 60 --

DR. SHEPARD: May I answer that question?

DR. MOSES: Yes.

DR. SHEPARD: In our desire to get as many cases in to AFIP as possible, we have encouraged VA hospitals to send in specimens, and it's possible that in that effort some people who are not appropriately in this group have been

submitted, and I think there is a problem in that there may be a few people who -- for example, you saw two infants. Obviously, they didn't serve in Vietnam.

DR. MOSES: I thought they were children of soldiers that did --

DR. IREY: That's right; they were.

DR. SHEPARD: Well, they probably were, but they should not be included in this registry. There are a few errors, but we're going to try and clean this up.

DR. IREY: Now, I thought it would be of interest to throw in a series of slides on the Skin Diagnoses because chloracne is credited with being -- while not absolutely diagnostic or pathognomonic, is frequently associated with and is accepted as evidence of a halogenated chlorine exposure.

We had 35 cases of dermatitis. These are various diagnoses, with the noun "dermatitis" followed by modifying adjectives of various sorts. Now, we've run these by the dermatology branch there, and so they have been of great assistance in splitting up this group.

This is still the dermatitis group. You can see the broad spread with non-specific chronic dermatitis being dominant. Number two there, with perivasculitis, is not a vasculitis, but the very common

perivascular infiltrate by lymphocytes.

The next largest group is the epidermal inclusion cyst, which I have already alluded to. This is an interesting finding. One explanation is that this is a superficial, subcutaneous tumor that is drawn to the attention of the Vietnam veteran because it's a lump, and he doesn't know what it is, and nobody knows what it is until it's taken out and examined.

The lipomas follow. There were eight nevi, and six basal cell cancers which I already alluded to.

Continuing in the skin group, there is a broad diagnostic spread, with small numbers in any one category.

I think this is the last one.

This is a preliminary report because we need more time to get more cases. Some of these low numbers that we have may be the nidus for a subsequent cluster, which only the increase in the number of cases and adequate sampling will bring out.

We also need more time to bring out the possibility of carcinogenesis in the Vietnam exposure group

because the latent period for environmental carcinogens may vary from a number of years up to three or four decades, such as asbestosis and pleural mesothelioma. We are about at the end of the first decade for the ones last to leave Vietnam, and we are about at the end of the second decade for those who were first there. So we're beginning to get into the latent period that might bring out tumors if they were related to Agent Orange exposure.

Now, should we get clusters of cases, we will then probably move from this cohort study to some form of a case-control study.

We realize the importance of statistical and epidemiologic coordination. Our statistician at the Institute has been following with us on this data and we're meeting, I think, before Thanksgiving with an epidemiolcgist and our statistician to go over this data and see if there is anything that might be of significance at this point and try to make plans for future activities, according to what direction we get from the pathologic examination of tissue.

Thank you very much.

DR. SHEPARD: Thank you very much, Dr. Irey.

Are there any questions from members of the committee to Dr. Irey?

Yes, Dr. Erickson.

DR. ERICKSON: Is there a directive to VA physicians that they should send all biopsy/autopsy material?

DR. SHEPARD: Yes.

DR. ERICKSON: I presume we're missing an awful lot --

DR. SHEPARD: Yes.

DR. ERICKSON: -- 400 cases.

DR. SHEPARD: I was going to bring up that point, but as long as you raised it, Dave -- one of the problems is that there appears to be a disregard of VA instruction, but there is a rational explanation for that.

To date, the Veterans Administration has not developed a process to identify Vietnam veterans, that is, veterans who actually served in Vietnam, as they are admitted to hospitals, in a way that would tag that individual and everything that happened to him while he's in a hospital or an outpatient clinic so that anything that flowed from that medical interface is able to be followed.

We are very anxious to develop such a process, and I think that's really the heart of the matter.

The specimens that have been submitted have been the result of individual physicians or groups of physicians who have responded to our continuing encouragement to be aware of this, to submit these tissues. But, clearly, and with,

certainly, the new legislation that's just been passed, we need to get a better handle on identifying people who actually served in Vietnam, for a whole bunch of reasons, and this is certainly one of them.

Do you have anything else, Dave?

DR. ERICKSON: No.

DR. IREY: Could I make a comment?

We are trying to establish or confirm that, in fact, the individual veteran on whom we have material did have service in Vietnam, and we've turned over the names of 300 of these 400 cases, the names of individuals with social security numbers, where we have that, and turned it over to the VA Central office in the hopes that from your records you might be able to give us confirmation and dates of Vietnam service.

I think the bottom line of this at this point, and as a preliminary finding, is that we have not found significant clusters that would point in the direction of the need for case-control-type epidemiologic studies. We're continuing to receive cases. For instance, we now have close to 600. I had to cut this off at some point and gather the data, and that was cut off at 400.

DR. SHEPARD: Yes, Dr. Moses.

DR. MOSES: I was wondering, are there any attempts going on at maybe some of the larger VA hospitals or on a

regional basis? All the autopsies that are done, anyway, or all the tissues, is there any way to look at that pathologically -- I mean, that would be a source being done, anyway -- and then to get a registry, sort of like a pathological registry, from each place and then put all of that together? And you're not as dependent on somebody sending it in. At least you know what you have in a particular hospital, and you might be more likely to get a larger number.

DR. SHEPARD: Certainly, each VA hospital that does autopsies maintains records of those autopsies. I'm not sure, but I understand --

DR. MOSES: Well, my question is that that might be a very interesting thing to look at if it could be identified. There are 172, 7 -- how many VA hospitals are there?

DR. SHEPARD: A hundred and seventy-two.

DR. MOSES: However many there are. If each one of those hospitals kept a -- which I know they do anyway. But if some way that information could be looked at as to who was a veteran and who wasn't and see if there's anything that's sort of piling up, because that information is there anyway.

I realize the advantage of going to one source is that it does go through one source and the same readers are looking at it.

It seems like that might be very useful information, since it's being done anyway. I don't know. It's just

a suggestion.

DR. SHEPARD: It's an excellent suggestion, and I wish we had the mechanism to put it into practice.

As I said, we still have not adopted, within the VA, a system tagging the people who served in Vietnam so that we could go back to those files and actually call out the records or the autopsy materials on a group of Vietnam veterans because we don't have them tagged, as such.

DR. MURPHY: Are there any kind of veterans groups tagged as such or --

DR. SHEPARD: Yes, they're tagged --

DR. MURPHY: -- Second World War veterans tagged --

DR. SHEPARD: Yes.

DR. MURPHY: What's the problem of tagging --

DR. SHEPARD: Because not everybody who served during the Vietnam Era went to Vietnam. There are some nine million people who served in the Armed Forces during the period of the Vietnam War, and only some two, two and a half to three million actually went to Vietnam or went near Vietnam. That distinction has not been made.

DR. MURPHY: That makes it different from other kinds of wars?

DR. MOSES: In terms of exposure, it does.

DR. MURPHY: Well, sure, but, I mean, I can't understand why this mechanism can't be put into effect if it's

been done for other kinds of veterans.

DR. SHEPARD: I didn't try to suggest that it can't be done. I think it should be done. I'm not aware of it having been done, for this kind of work, in any group of veterans.

I see -- is there anybody here -- Ms. Kilduff, could you answer that question? Do we tag combat veterans in other wars?

MS. KILDUFF: No. Like in World War II, we have not separated out European-Pacific areas, so this --

DR. IREY: Could I make a comment on that?

We realize the importance of time relationships, establishing when a lesion was first noticed against when they were in Vietnam. If we get peaks or clusters, then we will subject cases in those peaks or clusters to more detailed analysis, such as the time relationships.

Now, we do have some cases in which there's a skin biopsy, and the man had the skin lesion before he went to Vietnam. So, clearly, this is one that can't be attributed, in its initiation, to Vietnam service.

Other cases we have in which they had no lesion in Vietnam, a skin lesion, for instance, and eight years after leaving Vietnam they have a skin lesion. But because they have Vietnam service, the biopsy comes in. Now, this is

stretching the latent period too long, so those kind of cases would be eliminated, I think, from serious consideration as being Agent Orange related.

Right now we're looking for case clustering, which we haven't seen to this point. As has been reported in the recent international conference on dioxin in Arlington, other human studies have not as yet shown any significant clustering.

DR. SHEPARD: Yes, Dr. Gross.

DR. GROSS: Dr. Irey, I wonder if I can get your thoughts on a problem that I see here, and it's a problem that we also encounter in our own work.

You mentioned the payoff of this thing is the identification of clusters, and so on, peaks. Wouldn't it be true to say that the more specific the diagnoses -- and I know that the AFIP makes very specific diagnoses, but the more specific and detailed the diagnoses, the less likely one is to identify peaks or clusters or related findings?

We see that this is a problem that we face in the evaluation of toxicity from experimental animals. You have relatively few cases in your registry -- let's say a few hundred, 400, 600 -- and you have a great number of diagnoses so, as a consequence, most of your frequencies are one, two, three, and so on. The question that I have is, what mechanism is there to group or consolidate related findings? What is

your policy on this?

DR. IREY: Well, this is one reason why we are having a meeting with the statistician and the epidemiologist representatives to go over this data. That's one of the considerations we have in mind.

I'm going back on this cluster thesis to such things as asbestos and pleural mesothelioma and vinyl chloride and angiosarcomas of the liver and diethylstilbestrol and vaginal cancer, representing clusters relating to certain environmental factors as the sort of a thesis on which we were being guided here.

But your point is quite valid, and we're going to consult now with people who might bring that consideration into view.

DR. MOSES: Just to comment, I notice it's only eight cases, but there were no spindle cell carcinoma of the lung. That it wasn't present is rather interesting.

DR. IREY: Yes, yes. That's a good point because that's, I think, one of the more common lung cancer.

DR. MOSES: It's kind of interesting --

DR. IREY: Yes.

DR. MOSES: -- the small number of cases --

DR. IREY: And that would be an unusual feature in itself, then, yes.

DR. GROSS: Negative peak.

DR. MOSES: Yes.

DR. IREY: Yes.

DR. ERICKSON: At his age, probably not. They're peaked--

DR. MOSES: Well, we don't know how old these eight cases were. They might be all those older people.

DR. IREY: Well, the youngest-- and I mentioned it in a list of six cases with unusual lung features.

The youngest was 31, which is young for any kind of lung cancer. But most of them came from the older age group.

DR. SHEPARD: It's not terribly young for anaplastic carcinoma of the lung. It's a little bit unusual, but there are some anaplastic carcinoma of the lung that hit relatively young.

DR. IREY: Right.

DR. SHEPARD: Yes, Dr. Murphy.

DR. MURPHY: I'm not sure I know how you identify a cluster. Did I misunderstand you to say that lipoma was a cluster?

DR. IREY: Yes. It's made up --

DR. MURPHY: You considered that a cluster --

DR. IREY: Yes. It's one of the highest figures we have there. Now, I checked with --

DR. MURPHY: That's what I probably don't understand, how you identify what a cluster is. You had 153 -- well, I don't know -- lipoma. That's the highest single diagnosis or one of the highest single diagnoses you get, I guess, out of this 400 or so. But, on the other hand, when I see seven out of 17, I realize that's a distorted value. But seven carcinomas, metastatic or whatever they are, in the liver, out of 17 samples of liver, I wonder if that's not a cluster.

DR. IREY: Well, in the liver list, we're primarily interested in primary liver problems so that the largest single group there was metastatic cancer, which doesn't represent basically primary liver disease.

DR. MURPHY: I follow you.

DR. IREY: Okay.

Now, on the lipomas, these made up seven percent of this 408 cases, lipomas and angiolipomas. I checked with four laboratories --two veterans laboratories and one Navy and one civilian -- and asked the pathologists to give me the incidence of lipomas in their across-the-board routine, surgical path experience during a one year period. I asked them if they'd give me one pre-Vietnam and one post-Vietnam year, and most of them did. Their incidence of lipomas in the ordinary experience in their laboratories varied from a half a percent up to two. In our first 152 cases the lipomas, I think, averaged seven or

eight percent, and this is continued on, over the 400 mark.

So we tried to compare -- you asked how we identify a cluster. In this particularly large number in this series, we attempted to correlate that with the experience with other laboratories that weren't dealing primarily with this problem, and it came up maybe tenfold or fivefold above the ordinary experience.

DR. SHEPARD: Thank you very much, Dr. Irey. I think we'd better move along.

Next on the agenda, we'd like to hear from Mr. William Jayne, who represents ACTION, and who has some information to share with us on how ACTION is involved in the concerns of Vietnam veterans.

It's a real pleasure to have Mr. Jayne with us this morning.

ACTION VIETNAM VETERANS LEADERSHIP PROGRAM

MR. JAYNE: Thank you, Dr. Shepard.

In July of this year, President Reagan approved a new volunteer program in ACTION, called the Vietnam Veterans Leadership Program. What we're trying to do is put together voluntary programs in 50 cities around the country, where we have successful Vietnam veterans come forth to serve as volunteers in an effort to help solve the problems that some of their fellow veterans have.

I guess one of the best ways to describe the program

is to talk a little bit about what it's not. First of all, it's not an outreach-type program; it's not a service-delivery program, not a one-on-one helping idea.

What we want to do is have -- I think, as Dr. Shepard mentioned in response to a question a little bit earlier, there are about 2.4 to 2.7 million Americans who served in Vietnam. Among that group, many of them are very, very successful in business and in the professions, in academics, and in the arts. These are the people we want to reach as volunteers. These are the people we want to serve as volunteers.

We want them to help solve the problems of their fellow veterans by working at the senior levels of their communities -- economic, political, social -- in other words, to apply leverage to the problems.

It's not a big budget item, a big budget program. It's a very small program that will depend on true volunteers.

It's not a bureaucratic solution imposed by Washington. We're very much trying to make the program attuned to the needs of the local communities.

What we do is we've got a set of volunteers in a community. We do something that we call a "needs assessment," which is basically a diagnosis of the problem -- what are the major problems Vietnam veterans face in that area-- and then we develop a leadership plan, which is the specific goals and

objectives of the volunteers.

Another thing that the program is not is a panacea. It's not going to solve all the problems of Vietnam veterans. It's another thread in the fabric of Veteran services.

So far, we have programs in five cities. We expect to have 50 operating by the end of this fiscal year. We've got five now: in Philadelphia; Baltimore; Wilmington, Delaware; Nashville, Tennessee; and San Antonio, Texas.

We're just getting off the ground, but the response has been heartening. We've got a lot of good volunteers who have come forth, and I think we've got a lot of possibilities for success.

One of the areas that I've talked to Dr. Shepard about, where we can be helpful, is possibly in the Agent Orange area, working with the VA to try and schedule people to come in and get on the Agent Orange Registry, to take advantage of the services that the VA does provide at this point, as far as Agent Orange is concerned, and to try and help allay some of the fears that Vietnam veterans have, to at least get the process started.

We can also be of help, I think, in terms of publicizing some of those services that are available. I think the major problems the Vietnam veterans face across the country, the major problem, relates to employment: unemployment and underemployment. These are the substantive

type of problems that we're going to go after first. But if a guy doesn't have a job, it's more likely that he may have some trouble dealing with post-traumatic stress problems, anxiety over Agent Orange. I think all these things are related. So I think, in that sense, we may be able to help on the Agent Orange problem as well.

The Agent Orange issue, I think, of course, to Vietnam veterans, is a very, very real one, a very, very significant one. We know that our program, in particular, is not going to have a great impact on the solution of the problem, especially in terms of the scientific answers that are needed.

One message that we've been trying to put across as we have made some speeches, and so forth, across the country to the veterans group is that there is a group in Washington working in the Government, with intelligence and integrity, to try and solve the scientific problems. It's a tough one to get across, but I think that it's imperative that that message does get across because hysteria is not going to help in an area like this.

I think I've explained our program. The program is very much in its early stages, in its pilot stages. We haven't got a lot of success stories to talk about yet. We haven't got a lot of specifics to talk about yet.

I think I'd like to answer any questions that

anybody may have about the program.

DR. SHEPARD: Thank you, Bill.

Are there any questions from the committee?

DR. MOSES: How does this relate to the storefront service?

MR. JAYNE: It only relates to them in that we hope to be able to complement the veterans services that are out there, such as the outreach centers, the Vet centers, the community-based organizations that exist in many cities around the country, Department of Labor, veterans service organizations. It's not going to be a one-on-one outreach or a one-on-one-type counseling program. So we hope to be able to complement and make more effective the -- one of the things that we're trying to do -- it's difficult to talk about in substantive terms because it's a symbolic sort of idea. But I think that the Vietnam veterans, as a group, have suffered from an incorrect stereotype, the stereotype being that Vietnam veterans are victims, that they are to be pitied.

Vietnam veterans, by and large, have done well. They have readjusted well. This program is intended to show that to some degree.

One of the problems that Vietnam veterans have had is the problem in dealing with institutions of any kind. I know I felt that, myself, for many years, after coming back from Vietnam --that large institutions were to be mistrusted,

large institutions such as the VA.

I think that a better self-image among Vietnam veterans will help them deal with institutions, such as the VA, in a positive way.

DR. SHEPARD: Any other questions?

Will you be able to stay? There will probably be some questions from the floor when we complete the next point on the agenda.

MR. JAYNE: Sure.

DR. SHEPARD: Thank you very much, Bill.

I'd like now to call on Dr. Page to give us a brief update on the status of the VA Mortality Study.

Following this, we'll open up the meeting to discussions from the floor--questions, and so forth.

REPORT ON VA MORTALITY STUDY

DR. PAGE: Throughout most of this morning, we have been listening to reports of some of the extensive research, both planned and underway. The study which I am about to report on, the Vietnam Veteran Mortality Study, is being designed with a different purpose in mind. While this study will provide somewhat limited and somewhat less definitive health data, it should provide it in a relatively short time and provide it relatively inexpensively.

The study is designed to analyze and compare death rates of the veterans with service in Vietnam and compare them

to the death rates of Vietnam Era veterans who did not serve in Vietnam. It may be possible to also compare the death rates of both groups of veterans to that of non-veteran males of the same age in the U.S. population. At a still later date, we should be able to describe the causes of death among these groups.

The Vietnam Veteran Mortality Study will use existing computer records. It will collect information concerning deaths among veterans discharged from the Armed Forces after June 30, 1968. These are the earliest suitable automated data we could find. The study matches Department of Defense personnel records and Veterans Administration death benefit records providing reasonably accurate demographic data, military service data, and mortality data from these computer files.

The Vietnam Veterans Mortality Study will consist of five phases, although only the first three are described this morning. To begin the study, computer files will be generated from Veterans Administration and Department of Defense records. Subsequent phases of the study will use information obtained from death certificates.

The first phase will yield overall death rates for Vietnam service and non-Vietnam service personnel; the succeeding phases will yield mortality information by cause of death. In more detail, those three phases follow.

Phase I. The Veterans Administration automated death records and the Department of Defense automated personal records will be matched to produce files for analysis of overall mortality rates. These files will also support the other phases of the study.

Phase II. One or more state-computerized death certificate registries will be matched with the file of deaths created in Phase I. This matching will allow proportional mortality analysis of cause of death.

Phase III. A selection of random sample from the deaths will be made. Death certificates will be acquired and coded to be used in the study of mortality rates by cause of death.

Although these computer matching tasks are theoretically straightforward, practical snags can occur. For example, in matching computer records any error in the records, like transposing digits in a social security number or service date, could cause two records that should match not to match. In addition, records missing from files cause matching problems. For example, we know that most, but not all, veteran deaths are reported to the Veterans Administration.

Right now we are in the process of determining the extent of these problems and deciding how to handle their effects.

If all goes well, this study will provide a wealth

of information on the mortality experience of Vietnam Era veterans. Even so, it will not provide a complete medical picture of these veterans.

There are several reasons for this. First, the follow-up period is short; most Vietnam veterans are still young and are probably still alive, so that the complete picture of their mortality may not be available for many years.

Second, many medical problems do not cause or contribute to death, and the existence of such problems cannot be studied by mortality analysis.

Last, there is the question of cause and effect. From this study we will be able to determine only whether there is an excess or a deficit of deaths in one group versus the other. But we will not be able to tell what caused these differences.

The Vietnam Veteran Mortality Study should, nevertheless, provide the first large-scale analysis of deaths among Vietnam service and non-Vietnam service veterans. The study is, of course, only a part of the description of the health of the Vietnam veteran, since it is a study of mortality only. Yet, it is, I feel, a good starting point. By using existing computer records the study should produce solid results relatively quickly and inexpensively.

Testimony on the Vietnam Veteran Mortality Study was included in yesterday's testimony to the Senate Veterans

Affairs Committee. An oral presentation on the study design has been made to the Science Panel of the Agent Orange Working Group, and copies of a preliminary protocol have been given to Science Panel members. Plans are underway to form a steering committee, much like the Ranch Hand Study's advisory committee, to act in an oversight capacity for this study.

That's all I have to say. If there are any questions, I'll be pleased to handle them.

DR. SHEPARD: Yes, Dr. Moses.

DR. MOSES: Yes. I'm not familiar with these records or the protocol. Is only the physician-stated cause of death or, also, underlying or contributory causes that also can give a lot of information, will that information be included?

DR. PAGE: That's the function of what is on the death certificate. We haven't gathered those yet.

DR. MOSES: You said you're going to use computer tapes? Is that information on there, or do you know?

DR. PAGE: That's a function of the state registries then. In the Phase II, we'll be getting automated causes of death. That's a function of what they code.

DR. SHEPARD: I think if you could clarify exactly what record tapes you're talking about, you know, the BIRLS --

DR. MOSES: I thought he said they were going to

match -- oh, I thought the death record information was on computer tape. It's not?

DR. PAGE: No, not overall.

DR. MOSES: That's just to keep the people together to see if they're alive or not?

DR. PAGE: Well, I tried to split this out because there are three phases, and if you scramble the phases, you're in trouble.

In the first phase, DOD and VA records are matched. That gets us notice of death and death rates. In the secondary phase, we must go to state-computerized registries to get computerized cause of death. In the third phase, we go to death certificates to get full causes of death. We'd have to recode those some way.

DR. HODDER: DOD computer records will have the cause of death --

DR. MOSES: Oh, they do?

DR. HODDER: -- as part of the IPDS system.

DR. PAGE: We're not using DOD records to determine death causes.

DR. SHEPARD: Well, it's a possibility, though.

DR. PAGE: Yes.

DR. SHEPARD: I mean, we need to bear in mine that we --

DR. MOSES: That would be interesting to see what

the comparison would be between DOD and --

DR. SHEPARD: Yes, Dr. Lingeman.

DR. LINGEMAN: Dr. Spivey's proposal also includes a mortality study as part of the epidemiologic study. How will these two mortality studies differ? Are both necessary or is this a needless reduplication of effort?

DR. SHEPARD: If I may just conceptually answer that question -- first of all, we don't have a protocol yet from Dr. Spivey which outlines in detail how he will conduct that mortality study. He has referred to the fact that a mortality study should be done.

The VA has already put into place a process for doing a mortality study. I think one of the things that I'll be looking to this committee is to look at both of these protocols and see if they are in fact duplicative, see if they're complementary, see if they should both be done, or what.

That brings up what I was going to say next. We will be providing to the members of this committee a protocol for this mortality study for your review and solicit your comments.

Dr. Irey.

DR. IREY: You speak of getting your diagnoses from death certificate material. Will these be death certificates that have had a follow-up diagnosis after autopsy is completed

or the death certificate that is made out prior to taking the body to the undertaker, which -- sometimes it doesn't represent the findings at the ultimate autopsy study. Is there any comment on that?

DR. PAGE: Once again, this is probably going to be a very complicated study. In the Phase II, we're talking about State Vital Records. Whatever the death certificate is from the State Vital Record, that's what we will be using.

In further studies, we can actually go to autopsy records, medical records, and do these kinds of follow-ups.

DR. IREY: Does anybody know of a study in which the diagnosis made on the death certificate, on the day of death, that went to the undertaker, and then follow up with autopsy findings-- has there been any work on that?

DR. MOSES: Yes. I'll get you that reference. I don't know it right off the top of my head, but I know the study and I can get it to you. There was a big, big difference--

DR. IREY: What's the bottom line on that?

DR. MOSES: I can't remember. I think it was about 63 percent agreed. I think that's what it was. But there's a difference --

DR. IREY: It would have a --

DR. MOSES: I can -- in fact, the next meeting, I'll have that.

DR. IREY: -- thirty percent error, then?

DR. MOSES: Yes, about 33 percent did not agree. I think that's what it was, but that's really kind of off the top of my head. But there have been a couple of studies of that done.

DR. SHEPARD: I hope that nobody gets the impression that we will use solely the death certificate as the source of information outlying the cause of death. We all know that death certificates are really not adequate to that task.

However, it does serve the purpose of the fact as to establishing death. It would indicate some categories, probably, and would certainly serve to identify where the medical records reside in the event that a more detailed cause-of-death study needs to be done.

But, certainly, we will not base any, I don't think, valid detailed definition of cause of death based solely on death certificates. I think the best we can do is kind of groupings of illnesses.

Yes, Dr. Hodder.

DR. HODDER: Just a comment, although there are, obviously, substantial problems with death certificate data, if your controls and your cases are similar, I would be much happier using that data to give me a hint as to where to go to find the category/disease problem than I would if I have an uncontrolled denominator from which I'm getting cases referred. Then might have many, many different criteria so that I can't even go back,

and even
/I don't/have controls for them, or any idea what the selection process was. To me, death certificate data, where you have no reason to suspect there's a difference in the error in the controls versus the cases, would be far superior, I think, as a searching place for hypotheses.

DR. SHEPARD: Thank you, Dr. Hodder.

Are there any other comments from the committee?

Yes.

DR. ERICKSON: A question. I don't understand Phases IV and V.

DR. PAGE: I didn't say anything about Phases IV and V.

DR. ERICKSON: You didn't say anything about Phases -- well, what are Phases IV and V?

DR. PAGE: Phases IV and V depend on the first three phases.

(Laughter.)

We expect that if something shows up, we can look at high-risk subgroups. That's what we've called Phase IV. We have military occupation specialty. We can do those kinds of analyses. Phase V might be possible case-control subgroups. Again, that's a function if we find high disease profiles.

DR. SHEPARD: Dr. Kearney.

DR. KEARNEY: Just one comment. Do you all intend, Barclay, to talk about the registry revision or do you want to

go to the audience? I just have a comment on that before we leave.

DR. SHEPARD: Sure. I'd be happy to hear the comment. I had made some comments about the registry revision. We'll have something from which to solicit comments in a more graphic form, shortly. But if you have some comment, please feel free.

DR. KEARNEY: Yes. I just wondered, since we've gone to such depths to get this information and we have a number of people now reporting to the hospitals asking care, would it be helpful for us also to know their duties, their unit, the lengths of service, the place of service, and perhaps even a map grid where they could indicate where they served in Vietnam?

Now, it relates to what we've been doing in the White House situation with Mr. Christian and his records. And I want to commend DOD on the diligent manner in which they have responded to all of our requests, for both unclassified and classified documents.

For a little bit more, we might get some rather interesting information here to see if there are any specific units or any specific geographic regions where there is a number of people reporting some sickness. For not much more, we could get some very useful information.

DR. SHEPARD: That brings up a good point. I wasn't

planning to get into it. But let me just say that, as we look at this data from the registry, it seems to me we may have the opportunity to identify people who have rather specific recollections and accurate recollections of the nature and location of their exposure. If we use that group of individuals, bearing in mind this is a self-selected group--but if we use that group of individuals to start a search in the other direction, going to the personnel records to identify units, possibly that would give us a clue.

That's one of the things that I want to bring up at our next Science Panel meeting -- to discuss that possibility. We now, as I say, have some 68,000 and that's a sizable group. Of those, I think some 40 percent -- and I'm really guessing now, but I think that's somewhere near right -- have rather clear recollections as to where they served and how they were exposed. The majority, I think I'm accurate in saying, that recollection is not very clear.

Many of them say they don't even know if they were exposed. They just know that they were in Vietnam and they had the potential, therefore, of being exposed, and they are, therefore, worried about the possible health effects.

Quite a number of them now have rather specific recollections of where they served and how they were exposed. I think that may serve as a source of going at the search process from a slightly different direction and may be fruitful.

Yes, Dave.

DR. ERICKSON: When can the committee expect to receive this mortality study protocol?

DR. SHEPARD: We're in the process of smoothing it up a little bit, and we'll forward it to the members of the committee as quickly as that happens.

We got encouraged, strongly, by Dr. Houk -- we had made a commitment. I'll be very open about this. Dr. Houk asked me to provide the Science Panel members with a copy of the protocol. I had the impression the protocol was a little further along than it actually was -- this is the age of protocols -- so I guess I hastily made a commitment that that would be made available to the members of the committee. Knowing that -- the past Science Panel met last week, as you know, and we did provide a preliminary protocol. We want to smooth it up. We're in the process of doing that, and as soon as that gets accomplished, we will distribute it to the members of this committee.

Dr. Cordle.

DR. CORDLE: I have just one question to make sure I didn't misunderstand something here, and this goes to the questions that were asked by Dr. Murphy and Dr. Moses. Is there, in fact, in this matching process for the records between VA and DOD, a method of identifying whether or not service did take place in Vietnam?

DR. SHEPARD: As best we can tell, yes.

DR. CORDLE: Then I don't understand why you can't match the VA records in the hospitals in the same manner to decide --

DR. MOSES: Very good idea.

DR. CORDLE: -- who is a Vietnam veteran and who had service in Vietnam.

DR. SHEPARD: When those tapes are edited and wrinkles taken out of them, that may be a possibility. I see Dr. Page is rising. He's the expert in this area.

DR. PAGE: We have some legal issues. We can match dead people against DOD personnel records. We have trouble with --

DR. CORDLE: Well, these are dead people. If they've done the autopsies, they are.

DR. PAGE: People in the hospital autopsies, yes; VA hospital episodes, in general, no.

DR. CORDLE: I understand, but I think the question really came about the --

DR. MOSES: That's right.

DR. CORDLE: -- post-examinations.

DR. SHEPARD: Certainly, when we get this tape, I think there will distinctly be that possibility. That won't solve the problem, however, of pro-actively identifying these people. That's what I was alluding to earlier -- to put a

system in place in which people will be identified before they die.

DR. ERICKSON: What are the legal problems?

DR. PAGE: I'm not an authority on DOD records, but it's my understanding that, under the Privacy Act, and the way they have written there "routine use of that file," they cannot routinely release that file to us with names and identifiers on it.

We sent the deaths to them; they matched them. They did not release any -- they released aggregate, unidentified data to us.

DR. CORDLE: But isn't this, in turn, then going to raise all kinds of problems with the UCLA study if you can't identify individuals in the way that you are trying to? I don't understand how you can do the Epidemiological Study if you can't identify individuals by something other than just a number.

DR. SHEPARD: Dr. Hodder.

DR. HODDER:

There's a reason for health records personnel records being collected, and under the Privacy Act the individual must know that the record is going to be used for that. If there is a valid scientific protocol -- one of the reasons for collecting health records is research and, therefore, it is not a violation of privacy, given a protocol as approved by DOD --

at least, this is as far as I understand it -- given that the protocol is accepted by DOD, for example, the UCLA study. Then that would fit in with the reason for why that health record was collected and, therefore, will be valid to allow the investigators access to the records.

DR. CORDLE: So if they have a valid protocol, then they can follow the same procedure on your death records.

DR. PAGE: By and large, we don't have need for any individual identifiers. This is a study in which we are going to count causes. We don't need to know the fellow's name or his SS, then, to analyze the data.

DR. GROSS: But for follow-up, you would need it, wouldn't you?

DR. SHEPARD: You're talking about dead people.

DR. MOSES: Yes. But how do you find out where they were if you don't know what their names are?

DR. GROSS: He would want to look at clusters, unusual things, and so on.

DR. MOSES: Yes, right.

DR. PAGE: Yes, we have the identifying data for the dead people. We sent that to DOD. They did not release identifiers on living people, to us. They did not feel they were permitted.

Now, I should make it clear that we did not ask them to change their Privacy Act statement. We wanted to get

the data that we could analyze now. This is not to say that that could not be changed. But I don't know. I don't deal with those records directly.

DR. SHEPARD: Are there any other comments or questions from the committee? If not, I'd like to now open up discussion questions, and so forth, from the floor.

Would you please, if you have a question, use the microphone at hand.

COMMENTS AND DISCUSSION

DR. SHEPARD: I have one question that has been submitted to me in writing as follows: If a decision is made to expand the study -- that decision should be made soon -- will it have to come up with a new protocol? This is from John Terzano.

John, maybe you could amplify on exactly what you mean by expanding the study, because that sort of means different things to different people. It's a good question. I don't mean to downgrade it. I just want to make sure that we're understanding your question.

MR. TERZANO: If you expand the study to bring in the dapsone, Agent Blue and White and everything, as Congress has authorized, are we going to have to go through a whole new protocol design and everything, because UCLA isn't taking that into account right now.

DR. SHEPARD: That's correct.

It's my view on the whole issue of expansion of the study -- and I think this was brought out in the hearings yesterday -- that both a study focusing, to the extent that it can be focused, on Agent Orange exposure and a broader study should be done.

So I don't think it's going to be scrapping what we have now and going to the full Vietnam experience unless we're forced to do that, by virtue of the inability to identify an exposed group.

But let's assume for a moment that we are able to do a study focusing on Vietnam. I'm assuming an Agent Orange exposure as one of the considered variables. I don't think that we should, simply because we have the authority to expand the study, scrap that study and move into the total Vietnam experience. I think that would beg the issue as to whether or not Agent Orange has a potential for causing health problems.

MR. TERZANO: No, I think you can -- I agree. I think you can do both at the same time. But if you expand the study to service in Vietnam, what is that going to do to the protocol design?

DR. SHEPARD: Well, maybe I'm not making myself clear.

I think we need to maintain the study for focusing on Agent Orange exposure. I think that another study, an

additional study which might encompass that, should perhaps also be done. I don't think that it could be made -- or should be -- I should put it that way -- a part of this protocol.

This protocol has gone a considerable way in looking at military records, with a view to trying to establish an exposure index, if you will, on Agent Orange. So I think we should keep this motion going essentially along the direction that it is going. If another study seems advisable, to look at the larger question of what has service in Vietnam, what in fact does that have on human health, then I think it probably ought to be done as a separate effort.

MR. TERZANO: Well, can you not--in your exposure indices, if I remember correctly, UCLA had a high probability, low probability. Can you not use the high probability people to specifically look at Agent Orange and the low probability people service in Vietnam and you can do them both at the same time?

DR. SHEPARD: Okay, I get your point. Yes. And providing that there's a control group that never went to Vietnam --

MR. TERZANO: As a third group --

DR. SHEPARD: -- you can compare the low-exposure group to the non-Vietnam service, Vietnam Era group as a possible clue as to what some of the health hazards might have

been for a simple service in Vietnam.

However, in order to isolate some of the things that -- see, you said "broaden the study." But you also said "looking at other things, such as dapsone and other herbicides." That implies that you intend to focus on those issues. Now, if you're going to lump them all together, then that would be in part of a total Vietnam service study.

However, if you say "to look at other things, such as ..." then you're implying that those other things, those other variables, will be isolated in some fashion. I think that would then require a similar effort to what we're now trying to do with Agent Orange.

MR. TERZANO: Interesting.

DR. SHEPARD: Yes, John-- John Hansen.

MR. HANSEN: I'm John Hansen, from GAO. I have a question with regards to the mortality study that Dr. Page discussed.

When, specifically, did VA start developing plans to conduct a mortality study?

DR. SHEPARD: I can't remember the exact date, but this was a --

MR. HANSEN: Well, a month or a year ago?

DR. SHEPARD: About a year and a half ago.

MR. HANSEN: About a year and a half ago?

DR. SHEPARD: This came out as a suggestion from the Science Panel of the Interagency Work Group.

MR. HANSEN: Did UCLA know of VA's efforts in designing this mortality study before they designed their protocol?

DR. SHEPARD: I don't know.

Dr. Hobson, can you tell us about that?

DR. HOBSON: UCLA was asked to consider the entire range of studies that could be done to answer this question about Agent Orange on an epidemiological basis.

One of the things that they considered early, at the time that the contract was actually let, or even before that, was the consideration of a mortality study, which they went ahead and designed into it. They were told that discussion had been held both with the National Academy of Sciences' National Research Council for Medical Follow-Up agency and with our own people, concerning who would conduct a mortality study. This did not in any way impede their designing such a study in the course of their work on their protocol.

So the answer was -- I can't tell you exactly when along the line. But they were told that it was under consideration and that no component was to be -- no decision was to be made about any component and who was to carry it out prior to the completion of the protocol.

DR. SHEPARD: Does that answer your question, John?

MR. HANSEN: Yes. My understanding is that the mortality study that you had in mind sounds very similar to what UCLA proposed, using BIRLS Death Certificates, and comparing them with military records; is that right?

DR. SHEPARD: Yes, I think there are some similarities. I'm not sure about exactly how they proposed the matching because I'm not sure we have that level of detail in the protocol.

Larry.

DR. HOBSON: There is quite a detailed protocol included in their submission to us. Basically, it's the same kind of study. But that's almost given. The studies are not going to be very different if they deal with the same material in more or less the same fashion and to arrive at the same end. So you can expect a certain similarity in it.

I think there are things in their submission to us that we can well take into account in designing our own study if we carry it out, or they can certainly use a great deal that's being done here if someone else carries it out.

MR. HANSEN: Thank you.

DR. SHEPARD: Other questions?

MR. NEAVES: One question, please.

DR. SHEPARD: Would you identify yourself?

MR. NEAVES: Bill Neaves, from the University of Texas.

Further to the question of whether studies will be conducted on the basis of established exposure to Agent Orange or just to a service in Vietnam, I gathered from the comments that were made earlier this morning by Dr. Irey that the Armed Forces Institute of Pathology Study and the Agent Orange Registry is really based, not on an established linkage with Agent Orange, but just with service in Vietnam.

DR. SHEPARD: That's correct.

MR. NEAVES: Thank you.

DR. SHEPARD: Yes, Dr. Erickson.

DR. ERICKSON: Did I understand Dr. Hobson correctly to say that UCLA had submitted quite a detailed proposal on a mortality study?

DR. HOBSON: They had a great more detail on the mortality study in their submission than they did, for example, on the overall Epidemiological Study itself.

DR. ERICKSON: But this wasn't something in addition to what we've seen?

DR. HOBSON: No, no, nothing beyond that.

DR. SHEPARD: Yes.

MR. SUTTON: Yes, my name is Mike Sutton. I have a question for Major Brown, on the Ranch Hand Study.

In particular, since so much of the time today has

been on morbidity and mortality studies and what results we get from autopsies, the Ranch Hand Study is going to be a health follow-up as well.

My question is, I want to understand who with the Ranch Hand participants is going to be the cohort-control group. As I understood it from Major Brown, it's going to be other Southeast Asian, i.e., Vietnam in-country veterans; is that correct, Major Brown?

MAJOR BROWN: The control group is derived from another group of fliers and personnel that were either in Vietnam or Southeast Asia.

MR. SUTTON: This leads me to my real point. My point is that since we're concerned -- and the EPA, for example, is looking into -- 2,4,7,8-TCDD contamination. Here in the United States herbicides continue to be used. Why could not the Air Force use its available resources for non-Vietnam-service veteran service, in the United States and in Europe as a cohort group so that they might broaden their base on their results of the health hazards?

MAJOR BROWN: You're asking us to modify the design of the accepted protocol, and at the present time that protocol is locked. It has gone through a very rigorous review process, and to disrupt the protocol at this time would create a major change in the study. You don't want to do that.

The other thing is that you have a number of other factors operating in Vietnam that you would like to control for in your epidemiology study, for example, battle stress. If you control a -- or you include a population in the United States, those folks may not have undergone that type of situation. The living conditions in Vietnam were not necessarily the same as you find in the United States, also.

So we tried to find a control population that was as close to the Ranch Hand group in all other respects except for exposure to Herbicide Orange.

DR. SHEPARD: Does that answer your question?

MR. SUTTON: Well, if it's locked in, of course, it does. But I suggest that since we're looking at contamination from dioxins from other sources -- I mean, EPA is working on it -- that if this could be modified at some point, using these other veterans, I do think there should be another control outside of Southeast Asia. You've got two controls, both located with their experience in Southeast Asia. I believe the control needs to be expanded.

DR. SHEPARD: But you need to understand that that's deliberate in order to eliminate another big variable.

MR. SUTTON: Yes, Dr. Shepard, but then the amount of contaminations, sir, that were received, depending on where the veterans served, in the recent view or, rather, recent light of the admission that Agent Orange had been

dumped on groups of veterans, that it had not been known, since the herbs tapes are not completely accurate, since their contamination could have varied from what a citizen in the United States would have received to far more contamination than a Ranch Hand who has been trained to handle material, I'm suggesting your variable is almost like comparing two groups that had had equal opportunity for contamination, depending on their training and where they were located. Taking veterans who served in Europe and the United States as a control group, at least a third control group, might allow for some of this knowledge--incomplete knowledge on how much was sprayed, when and where and at what time, in Vietnam.

MAJOR BROWN: One point, in terms of the exposure, you're talking about the -- on dumping, you're talking about accute exposure, one, maybe--a finite number of times that a person was exposed while in Vietnam, if he was on the ground and happened to be in the vicinity when the jettison occurred.

In terms of the Ranch Hands, they flew these planes every day. They were exposed every day that they were in Vietnam. So there you have a chronic exposure.

Historically and scientifically, we found that chronic exposure generally creates a greater hazard, particularly for chronic disease, than does accute exposure.

DR. SHEPARD: Are there other questions?

Yes, sir.

MR. BACKSTROM: Yes. Tim Backstrom, EPA. I'm curious -- I have a question for Major Brown about the Ranch Hand Study.

Since the agents Purple and Pink, which were used early in the Vietnam conflict, are thought to have been somewhat more contaminated and there's also been a longer potential period in which effects might be noticed, I'm wondering whether or not any attempt has been made to identify a subgroup of people who may have been exposed to those agents.

MAJOR BROWN: The Ranch Hand Study incorporates all Air Force personnel that were part of the Ranch Hand organization. In the early years, 1962 through 1965, Purple and Pink were sprayed by the Ranch Hands. They also, in the later years and in those years, sprayed Blue, as well as White.

There is an opportunity, depending on what is observed in the study, to try to differentiate. And, yes, people who sprayed Purple and Pink are included in the study. You must realize, however, that the number of individuals that were involved in that portion of the operation are smaller in number than compared to the larger group.

DR. SHEPARD: Any other questions or comments from the floor?

I would like the record to note that we have devoted -- or made the opportunity for considerable comment and question from the floor. There was some suggestion that the agenda was skewed in the direction of precluding adequate discussion from the floor, and I just want to have it clear that that does not appear to be the case today.

Our next meeting will be sometime three months from now. The 19th of the month seems to be a favored date. I don't know. I guess it works out that way.

Thank you very much for coming. I would like to reiterate the comments of Mr. Hagel in appreciation for the work and diligence of our committee here. I really appreciate all your efforts and input, and we will continue to rely on your good offices.

I would also like to recognize the continued interest on the part of many of the people who come to these meetings and give us their input. We consider that a very valuable resource, and we hope that it will continue.

Lastly, I would like to express my deep appreciation for the members of my staff who have worked so diligently the last few days, not only to put this meeting together, but to get ready for the hearings that were held yesterday, and also to put together, which are now available for those who would like them, the Chief Medical Director's guidelines for the implementation of Public Law 97-72. Thank you.

(Whereupon, at 11:35 a.m., the meeting was adjourned.)

CERTIFICATE

This is to certify that the attached proceedings before the Department: Veterans Administration

In the matter of:

Veterans Administration, Advisory Committee on Health-Related Effects of Herbicides, Thursday, November 19, 1981.

were had as therein appears, and that this is the original transcript thereof for the files of the Department.

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I hereby certify that the proceedings and evidence herein are contained fully and accurately, as corrected.

Barclay M. Shepard

BARCLAY M. SHEPARD, M.D.
Chairman, Advisory Committee on Health-Related Effects of Herbicides

March 28, 1982

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

(Eleventh Meeting
February 25, 1982)

May 1982

Washington DC 20420

VETERANS ADMINISTRATION

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ADVISORY COMMITTEE ON HEALTH-RELATED
EFFECTS OF HERBICIDES

- - -

Veterans Administration
Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Thursday, February 25, 1982

The Committee met, pursuant to notice, at 8:30 o'clock, a.m., BARCLAY M. SHEPARD, M.D., Chairman presiding.

MEMBERS PRESENT:

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ALTERNATES:

(For ALBERT C. KOLBYE, JR., M.D.)
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PROCEEDINGS

(8:30 a.m.)

CALL TO ORDER AND OPENING REMARKS

DR. SHEPARD: Good morning, ladies and gentlemen. Welcome to our quarterly meeting of the Advisory Committee on Health-Related Effects of Herbicides.

We're happy to have you all here this morning. And we have a fairly full agenda, so I think we better get started.

You will notice that the subject of the epidemiological study protocol is not on the agenda. The reason is that we weren't quite sure where we would be with that at this point. But the members of the Committee have now been provided with an abridged version of the protocol. And I might just say a word about that.

I think you will realize that certain portions of a protocol must be held in confidence in order that the study will not be adversely biased or the quality of the study will not be adversely affected.

So, that after consultation with a number of experts in this area, the VA decided to make the appropriate abridgements of those elements of the protocol which were felt to be appropriately held in confidence.

In essence, the abridged portions are the

questionnaire and certain documents relating to physical examinations and data collecting documents.

The ingredients, or the essential ingredients, I should say, of the methodology for conducting the study are all included in the copies that have been distributed. So, I think that you have in front of you the essential elements of the protocol.

And we would like very much for the Committee to review this and provide us with their comments.

As we have done previously, the protocol has been distributed to certain other review groups, including the Office of Technology Assessment and the Science Panel of the Agent Orange Working Group.

Those reviews are currently under way, and we hope to have comments back in the relatively near future so that the contractor may prepare his final submission. That is due into the VA 30 days following the formal presentation of the review comments.

We feel that -- and I hope that those of you who are now seeing this will agree -- that we have a considerably more polished and more complete, more useable protocol than was the case with the original submission.

I think the investigators at UCLA have now come in with what we feel is

a workable document.

I would like to ask the members of the Committee to provide me with their comments by the first -- excuse me -- I should have a calendar -- within three weeks from today, if at all possible.

I realize that that's a rigorous imposition on you, but we do need to get the comments back and get them to UCLA so that we can proceed.

So, if you please, will you have your comments to me no later than three weeks from today. I would appreciate it very much.

I think we will have by then the comments from the Office of Technology Assessment and also from the Science Panel. We had a meeting yesterday, and that process is moving along very well.

I'd like now to introduce to you, again, our Deputy Administrator, Mr. Charles Hagel, who, as you know, has taken a very vital interest in the whole Agent Orange effort, and I'm sure he will have some interesting things to report to you this morning.

Good morning, sir.

REMARKS BY DEPUTY ADMINISTRATOR

MR. HAGEL: Barclay, thank you. And good morning. It's nice to see Barclay back from the Caribbean. Are you keeping that a secret, Barclay? (Laughter.)

That's one of the pluses and the privileges of working for the VA. We let our people off once a month and they go to the Caribbean.

Well, with Barclay Shepard back and Al Young back in fine tune, we, once again, have a complete team and I'm very, very pleased to see that.

In about 30 minutes, we will be getting to all of you a copy of a memo* that I am sending out to our VA Agent Orange Policy Coordinating Committee that will set out, in some detail, some of the new developments that we are putting forth in regard to trying to upgrade and re-evaluate, re-organize our entire Agent Orange effort.

Barclay Shepard, and Larry Hobson, and Al Young, and Layne Drash, and Fred Conway and all who have been part of this for a long time really were the base from which we started and would also, at this time, like to thank them for that effort and for their help in organizing what we think is a pretty solid beginning to get to where we want to go.

I think, as everyone understands, this is a pretty fleeting and elusive issue, and it's going to take, I think, even more dedication in the future than we all have put forth to try and find some solid answers to this.

Also, I don't know if you have introduced Dr. Woodward to this group. We are very pleased to have

*See pages 100-103

Dr. Woodward part of our efforts. And he has very graciously consented to give us some time and to act as one of our consultants and one of our guiding beacons here in helping us establish some credibility, and also giving us some advice on -- if we're getting off the track or if we're on the right track. So, we're pleased to have Dr. Woodward part of this. Thank you.

In the memo which I will just briefly skirt over, but it'll go into some detail, we will officially announce that we are organizing a new Agent Orange Research Education Office; that we will have new and more office space than we have had before; we will be bringing in more people.

Dr. Don Custis, our Chief Medical Director, has been a very important element in helping us organize this. Barclay Shepard's people, the Environmental Medicine Operation within DM&S, will obviously continue to be one of the focal points and the leading elements of our overall direction in what we're trying to accomplish here.

Joe Mancias, who is our Assistant Administrator for Public Information, Consumer Affairs, is, at the present time and has been for the last three months, undertaking a massive outreach program to -- for the first time, I think -- at least that I'm aware of in the VA -- to go out and try and reach those Vietnam veterans off of the registry. There are 76,000 or so who have taken a physical

and have gotten their names on the registry, We'll also be using other rolls we have within the VA to primarily reach out to these Vietnam veterans who have obviously expressed concern about possible exposure and affects -- to Agent Orange.

We'll be updating them with periodic messages, bulletins, brochures on what we're doing, what the latest scientific evidence is. And this is -- this will be an ongoing process, and we think that will do much to try and take some of the raw emotion out of this issue.

And hopefully we'll be able to bring people back down into an arena where we can deal with facts and substance and also let people know that the VA is making every effort to try and come to grips with finding an answer to this problem.

Also within that memo, you will see some of the specific areas, research-wise, that we're involved in. Dr. Custis, through the coordination of Dr. Shepard and his people, about two months ago sent to all our 172 Medical Directors of our 172 hospitals invitations for them to submit proposals -- protocols -- on what we could finance within the VA with our research monies.

I think at the present time we are reviewing about 38 projects from 31 medical centers.

Dr. Custis has agreed that he would apply more

of our research monies towards Agent Orange proposals and we're excited about the prospect that we'll have some new adventures in that area that we haven't seen before.

I won't venture into the epidemiological study or some of the other areas that I think Barclay will cover or this panel will cover, but I think, maybe, in summary, I would say that I'm as excited about the prospects of this year on what we got out in front of us, both within the VA and all of you who represent various constituents who are all interested in finding a solution to this question, that I think that we've got a good start.

And I can tell you that the VA is pledged to just continuing that effort and trying to build on it and strengthen it. And we'll do everything that we can and more to work with all of you to try and find some answers.

Again, I want to thank each of you, because I appreciate the time that it takes to attend these meetings and give us some guidance and some counsel. And that's very effective, and also, it's very helpful for us.

And, again, I want to thank Barclay Shepard for his efforts, because without Barclay and his team, we would have had nowhere to start.

And, Shepard, as long as he stays in-country, will probably get something done this year.

With that, thank you very much, and the last

thing I really wanted to do -- and if this is okay, Barclay, would be to introduce Maurice LeVois, who I think most of you know.

Maurice is going to be the new Director of the Agent Orange Research and Education Office, and will work directly with Barclay and all of our people.

That office will report directly to me and we'll try to marry what we've got within DM&S and Barclay's office on Environmental Medicine with this new office, which we hope will become focal point that we can funnel everything in to.

So, with that, thank you. And, Maurice, we'd like you to say something.

VA AGENT ORANGE PROGRAM REORGANIZATION

MR. LEVOIS: All right. I'd like to thank you.

And I think that what Chuck has said is really the important information that we can give you in general terms.

The memo that's coming out will spell out in a little bit more detail what exactly what we're talking about in terms of an organizational placement and function of what we're calling now the Agent Orange Research and Education Office.

Just very briefly, the ideas that it cross-cuts the whole agency -- the intention is to work more closely

with the Working Group, Science Panel, this body, which we hope to renew our interest in getting advice and guidance from this body.

We want to coordinate our effort to streamline it, to become more responsive in general. We will be taking a keen interest in the research projects, not only the ones that are under way, but in producing more research out of the VA in this area.

We're definitely going to push to upgrade our effort to inform and educate, to reach out to concerned veterans, to provide a focal point for all the education efforts and information efforts that are going on throughout the states to inventory who's doing what in all the service organizations, all the state veterans' organizations and agencies.

And, in general, play the leading role that we should play in a Federal effort and nationwide effort to address the problems of Agent Orange.

I think that Chuck really has covered the rest of what I was going to say, which is that we have a renewed interest. And we're really excited about the possibility of doing something, working closely with you and seeing some action.

The most important factor, I believe, at this point is a renewed vitality in the VA's approach to things,

and I'd just direct your attention to the memo for further comments that I would make.

DR. SHEPARD: Thank you, Maurice.

I'd just like to say that I think that this sort of renewed effort -- perhaps some redirection and increased energy is to me, personally, a very heartwarming sign.

As you all know, we've been struggling with this issue. With the change of Administration there was a time when, I think, that we were all not quite sure of what was going to happen next in this whole area.

And now I think we have come together and now have a very solid approach to a problem which has been, at best, difficult to deal with.

We certainly don't anticipate that we'll be able to solve all of the problems overnight. But I think with this renewed energy and coordination that we're going to really make some progress.

I personally am very happy to have Mr. Hagel's personal interest in this area. Maurice and I have gotten to know each other pretty well over the last few weeks. I think that we're going to charge on together in a heads-up fashion.

So, I appreciate both of you being here and please feel free to stay as long as your busy schedules will allow you.

Just a couple of housekeeping remarks. For those of you who have no signed in, we like to keep tabs on -- not tabs, excuse me. (Laughter.)

We like to know who's here and whom you represent and, so, we ask that you sign in the book -- those of you who have not.

There will, as in past meetings, be opportunity for questions. Any of you who have questions and would like to direct them to members of the Committee, please write them out on cards and Don Rosenblum, the able Executive Secretary of this group, will be happy to forward them to us, and we'll discuss them at the appropriate time on the agenda.

I'd like now to call on Dr. Hobson to discuss the status of our Agent Orange Registry.

UPDATE ON VA AGENT ORANGE REGISTRY

DR. HOBSON: You'll notice on your agenda that Layne Drash is supposed to present this. The VA is very generous to its employees and, as you heard, Layne Drash has been given due time off to use his muscle moving furniture. So, I'm filling in for him.

A few rather administrative items in conjunction with this Registry may be of interest to you. We are in the process of getting out a circular that will allowus to contact all of the people in the Registry and obtain an updated

address as well as to inquire about their current state of health.

It seems very simple to put this together and it turns out to be, but it is also a very lengthy process in the Federal Government to get such a thing approved through all the necessary authorities outside the VA rather than in.

As soon as that is done, which we hope will be within the next few weeks, we will go out with a system of updating the address and the health information on each registrant.

We are also in the process and near the end of revising the circular which has the directions for the local hospitals in running the Registry, and in revising the reporting form, the so-called Code Sheet, so that the information that we get in here is in a better form and one that is easier to handle.

With that out of the way, perhaps you'd be interested in some of the figures. As of December 31st, of last year, there were a total of 76,316 individuals who had been examined for the Agent Orange Registry.

As of January 31st, 53,375 had been entered into the computerized Registry.

It has been emphasized over and over again that this is not an epidemiological study; that this is a self-selected population and we do not know what proportion of

involved people it really represents, nor do we have any assurance whatsoever that this is a random sample and is unbiased.

So that about all we can do is to look at comparative figures within this framework. You may be interested that a very careful look at some 50,000 of these individuals showed that only about 1 percent had either a malignancy or history of malignancy.

And what's more important is that those had about the same distribution that one would expect for different kinds of cancers within this age group. The most common one was skin.

And those of you who have medical knowledge know that many of the things that are called skin cancers are of a very low level of malignancy. They're usually due to the exposure to sunshine. They appear in farmers and people who are outdoors a great deal.

There were also represented testicular tumors which are common in young men -- relatively common in comparison to older men and it was no surprise that they were there and Hodgkin's Disease which is not a rare form of cancer either.

In other words, we can't find anything in this cursory look that suggests that cancer is a particular hazard to this group of people or that there is a particular

kind of cancer that appears.

Now, I want to caution again, this is not an epidemiological study. It cannot be said that this represents a true incidence. All that we can say is we have no indication that there is an unusually high incidence involved.

I would be happy to answer any questions that I am able about the Registry at this time.

DR. KEARNEY: Larry, when do you anticipate releasing pieces of information as you have done this morning. In other words, are you going to periodically tell us or give us a piece of paper that says what you've said this morning?

DR. HOBSON: We have considered doing this. We have been also cautious about trying to give any interpretation. I hope I've been cautious enough this morning not to arouse any particular interest in it.

We're not finding anything that really leads us to believe we have anything unusual or exciting. We are in the process of doing as much as we can of looking at the various things that have been reported in the group

and I hope that within the next six months or so, we'll be able to come out with a more concerted picture. But it still does not represent an epidemiological study or a true incidence scientifically.

DR. KEARNEY: I always question these milestones.

What's your next milestone?

DR. HOBSON: Our next milestone, actually, deals with the administrative side of getting the circular out and getting better information in here so that we can give you a better estimate than we can do right now.

That milestone is conditioned, really, on what the OMB and other people are going to do with our requests for updates.

DR. KEARNEY: When is this going to occur? June? July?

DR. HOBSON: You mean, when are we going to get it to them?

DR. KEARNEY: Yes.

DR. HOBSON: We'll get the first piece to them, I hope, within the next week or so -- two weeks. The next piece should go over within a month or two. How soon the OMB handles it is out of our hands, of course, and we hope that we can get a high priority and get it through them in about a month or so.

DR. SHEPARD: Yes, Tom?

DR. FITZGERALD: Larry, Mr. Hagel said that he intended to keep the group informed -- the veterans informed as to the progress of what's going on.

I think what you've just presented here would be extremely important in that updating of information, because

most of us are concerned about the undue alarm that has been raised, that is affecting the lives of the individual veterans. And certainly the information that you've just given should be reassuring to them.

MR. LEVOIS: If I could respond. I think that we intend to release this information now, and periodically, from now on.

There's absolutely no reason not to with the caveats that Larry has expressed, which is these represent considerably less than -- at this point, probably, 5 percent, 4 percent, of the possible veterans that could have gotten into the Registry.

Even in the most ambitious states, the largest percentage of representation that we've been able to get is under 10 percent. That may not be true in Minnesota. Fifteen percent or so there?

DR. SHEPARD: I would guess something like that.

MR. LEVOIS: The point is that these are self-selected and they're the most concerned. And it's very likely that the reason these people are the most concerned is because they have some sort of symptoms; that if you're only getting 10 percent of your people coming, one has to wonder which 10 percent is choosing to come and get on the Registry.

If we could see more effort such as both of these

which are very fine state self-help pamphlets that have been put out. (Indicating.)

They're encouraging everyone to come in and get on the Registry. Then we would have more faith in the fact that it was somewhat representative of healthy as well as not healthy people.

But the expectation is at this point -- that we're seeing a large number of somewhat more unhealthy people, because of the nature of the self-selection factor at work.

So, when we release the statistics, if someone runs -- trots off to vital statistics tables and tries to compare these -- this distribution of illnesses with the normal population, there is the expectation that you will see more of everything.

And I believe that we are, in fact, encountering that there is no disproportion on anything within the sample. And that's what we're looking at.

DR. HOBSON: There's one other thing that I might say for the benefit of those who are not really acquainted with our Registry; of this 76,000 plus individuals, there are only about one-third of them who complain of symptoms or diseases.

The balance -- the two-thirds -- are the worried well. They are concerned that maybe something will happen to them, but at present they are healthy.

So, this does not represent 76,000 ill individuals, or even symptomatic individuals who are coming in.

DR. SHEPARD: Thank you, Larry.

Let me just also say that we do plan to submit -- we don't have the figures. What Larry has just shared with you in terms of the malignancies is as a result of a very recent analyses of our data and we have not, you know, laid it out in a format suitable for distribution. But we certainly will do that in the very near future.

DR. ERICKSON: Barclay?

DR. SHEPARD: Yes?

DR. ERICKSON: May I ask a question about the protocol before we go on?

DR. SHEPARD: Yes.

DR. ERICKSON: Who is it that is reviewing the questionnaire and physical examination procedures?

DR. SHEPARD: There have been certain individuals within the peer review groups that I mentioned, the Office of Technology Assessment, the Science Panel of the Agent Orange Working Group, who have reviewed the entire protocol.

DR. ERICKSON: And are those reviews available for our benefit?

DR. SHEPARD: Yes. They are in process. They're

not available yet, because they haven't been completed. They are in process. Perhaps Larry can tell us when the OTA review is scheduled.

DR. HOBSON: The OTA review is expected within about two weeks. They hope to get it done. I can't give you the time for the Science Panel, although tentatively it has been set for about the same period.

These forms have also been reviewed by us in here.

I can give you this much: they are not expected to be the form that is finally used.

In the first place, they did what most of us do in the preparation of a protocol; they put in everything they could think of. And the result is some enormously long questionnaires and enormously long forms.

They will be, I'm sure, revised and then they will be use tested, field tested, and as a result of that, they'll be revised again so that the current format of them is probably not going to be the final one. We would not expect it to be. I'm sure you went through this with your questionnaire, too.

DR. ERICKSON: I'm not sure I understand the point of this embargo. I wonder if you might -- I expect there are other people who don't understand that point. I wonder if you would mind -- just tell us a little bit about that.

DR. HOBSON: You mean the reason for --

DR. ERICKSON: Not sharing the questionnaire with all concerned or anyone interested, especially seeing that it may be revised substantially.

DR. SHEPARD: There was a concern that if the questionnaire became public knowledge that it might affect the outcome of the study. And for that reason, a group of individuals was selected to review the total protocol, and also substantiate the fact that public knowledge of the questionnaire had the potential of affecting the outcome of the study.

DR. HOBSON: Dave, we questioned a number of epidemiologists about the advisability of releasing this portion of the protocol.

We didn't get an absolutely uniform/consistent or "Don't do it," but we got very close to that. As a result we decided to follow their advice. They based it on several different grounds, as I understand it but I don't want to give you a second-hand interpretation of their reasons.

This was not a decision that was made in-house. It was made after consulting a number of individuals who had seen the forms.

DR. SHEPARD: Yes, Dr. FitzGerald?

DR. FITZGERALD: I think I would like to go on record here as saying that I think it's sort of an ostrich-

like syndrome that you're exhibiting here. Any questionnaire is going to become public knowledge shortly after it is used a few times. The assumption being that there would be misuse of the symptomatology, then it would be inherent upon your study to have safeguards to be able to evaluate the interrogation that is being made of the individual rather than going into the secrecy route which is going to raise questions and doubts in peoples' minds that I think really is unfounded, but will seriously handicap the confidence in your study.

DR. SHEPARD: Well, I certainly understand your point of view. And I hope that as the process evolves, that those who feel that they would like to review elements of the questionnaire that issue will be discussed.

I think you can appreciate, as did the researchers dealing with the Ranch Hand Study and the Australians doing their study, that at least as a first go-around the sensitive elements of the protocol had to be held in some confidence.

We're very much in that initial review phase still. And -- so that we haven't gotten a final product yet. And it may well be that when the final product is released that this whole issue of confidentiality and so forth will be discussed in greater depth.

Yes, Larry?

DR. HOBSON: Tom, I might say that this has been one of the most debated and one of the most, I guess, questionable things about the handling of the whole protocol for us internally as well as externally.

We didn't come at this lightly. We knew it was going to cause a great deal of controversy. Not all of us believed that it was necessary to begin with.

It was advised by UCLA and that's what opened the question as to whether we should do it.

I think we have acted on the best advice we could get and I guess we will just have to stand by that.

DR. SHEPARD: Let me also share with you that this is not -- should not be -- I hope is not interpreted as revealing any lack of confidence in the membership or the individuals on this Committee. Please, let me make that clear. That's certainly the issue, not the intent.

I think if we had our "druthers" so to speak, we would have shared the entire protocol with everybody that we felt that could make a significant contribution to the review process.

Unfortunately, circumstances don't always allow the total treatment of this in a uniform fashion. And I think that as time goes on, we'll come to, I hope, a reasonable consensus on this.

DR. FITZGERALD: Let me respond to that. That is

a concern of mine. If, indeed, this is an Advisory Committee, that, indeed, we would be asked for limited advice. It brings up the question of the purpose of this Committee and the appropriateness of it.

I don't think you can divorce it, Barclay. It's a situation that is here. And as long as you go to secrecy, you are bound to raise doubts. And if, indeed, you have an Advisory Panel that is not sharing in the total protocol, then the question of the validity of this Panel has to be raised.

DR. SHEPARD: I certainly appreciate your comments and -- thank you.

MR. MULLEN: Dr. Shepard?

DR. SHEPARD: Yes?

MR. MULLEN: May I say something? What I can't understand is we have counterparts in these organizations sitting on the OTA Panel. They had the protocol.

From what I understand, the questionnaire portion and physical examination portions were the only things that were deleted.

We are now getting the same thing. The VA's had this since the 25th of January. Therefore, from what I understand, if the question over parts is still questionable, why didn't -- why weren't we supplied with the remainder of the protocol for review?

DR. SHEPARD: You mean prior to this time?

MR. MULLEN: Prior to this time.

DR. SHEPARD: Okay, that -- actually the final decision as to the portions to be abridged was a relatively recent decision, within the last week or so.

We could have mailed them out, I guess as long ago as four or five days ago when the copies were made, but we thought that since the Committee would be gathering at this time that we would simply distribute it at this time.

There was no intent to short-circuit any process.

DR. KEARNEY: Let me say something in defense of your -- the issue, as I understand it, working outside the VA, is that there was a legal and a scientific issue -- and meaning no disrespect to anyone -- but whenever there's a legal and scientific issue, the scientific issue usually is -- I think that's probably what we're faced with here.

Largely, a legal issue has some merit I suppose, but I don't understand all the ramifications of it, but I think it's -- it's happened before.

And I can appreciate your point of view on the thing. Barclay, I believe, probably -- you represent a more scientific approach to the thing, but you have constraints, and that is why we are where we are.

But it's not history. If you look at the history

of science and legal matters, scientific always takes second place. Right?

And that's why we're in this dilemma. So, if you're trying to defend it -- and I appreciate that, but I think I probably understand where you stand on the issue about having to say your personal point of view. And there are important, I suppose, legal ramifications in this. But they're hard to see.

MR. LEVOIS: I'd like to respond to Mr. Mullen. OTA got exactly the same material that you have now. They got it on the 16th. The process was not complete.

They were on the phone every day for the half week preceeding that trying to get consensus among the reviewers so that they could have something to show their panel before we were completed with the process.

We didn't even get official, written recommendations from them -- and they were part of the panel that reviewed it for the confidential sections -- until after they had distributed it.

So, they were in front of us. They were actually out in front of us in terms of where the process was.

I want to emphasize that this decision is not written in concrete. That we are still aware that we have -- I mean, it is a dilemma. There is -- there was unanimous --

although the reasons differ, there was unanimous judgment on the part of the epidemiologists that reviewed it that the sections that were withheld should have been withheld for the time being.

That, in one case, was sold on the basis of these are scientific working papers. And until this process is honed down -- everyone, for instance, criticized the questionnaire for being excessively long, unworkably long. There were four pages of questions on wax in the ears.

We're not going to go with that questionnaire. It's definitely going to be re-worded substantially. It will be pared down, probably.

We're still dealing with the problem of how do you make the trade-off between a study that has to be scientifically valid to be worth the money that it's going to take to do the study.

And a study that has to have the credibility to be worth doing -- so, we have a real problem. And we will appreciate your input and your advice.

But I hope you will appreciate our dilemma, because there was unanimous consent that it could bias the study were every question and every physical exam component released prior to doing the study.

MR. MULLEN: My point still is we're getting the same piece of material that OTA panel had to begin with.

Apparently, anything that was subject to any legal process was already removed.

Now, we've got three weeks to review this thing and comment. I'm sure everybody on this panel would have appreciated that extra week, because it is rather voluminous.

DR. SHEPARD: Yes, Dick?

DR. HODDER: I appreciate the concerns you have. It seems as though we've spent a fair amount of time -- and the Committee has been in existence before I was on it -- trying to develop a protocol. I don't think it's really going to jeopardize us very much if the Committee had to wait another meeting cycle before they could see it.

I don't think I'd like to jeopardize the study. And as you said, it's an interim document.

So, I'm not too concerned about waiting another three months to see it. What I am concerned about is perhaps we could still be an advisor in another way. The thing that bothers me about the UCLA procotol from before is the concern with secrecy of the questionnaire methods. That's clearly one way of trying to protect the study from bias, but it's probably the least effective way.

Once you start asking a questionnaire, or once you have so many people interviewing it, it's going to become

public to a certain extent.

I'd like to recommend that, in fact, it's more important to use the exposure/non-exposure index as the way of maintaining secrecy. That index is only generated out of one office, which means a much smaller chance of a leak and also, a much more controllable way of keeping secrecy.

The second point is that dissemination of information on a protocol, if they're concerned about veterans' bias, actually works against the veteran.

If a control overstates his symptoms he's, in fact, narrowing the difference between the case and the control. So that the source of bias would actually work against the veteran or against the person who you're concerned about overreacting to the information.

I think that some feedback should go to the UCLA people that they are taking the wrong tack in trying to protect the study.

DR. SHEPARD: I'd like next to call on Dr. Hobson again, to discuss briefly the matter of the new legislation relating to eligibility for treatment of veterans exposed to Agent Orange and also as a corollary the matter of ionizing radiation since these were a part of

the same public law.

DR. HOBSON: I'm sure that all of you here know that Public Law 97-72 said that the Veterans Administration would render medical care to individuals who had been exposed to Agent Orange and/or ionizing radiation for conditions that could be attributable to those exposures.

The legislative history made it clear that the Congress wanted this liberally interpreted by the Veterans Administration.

In response to that law, the Veterans Administration published in the December 2nd Federal Register two proposed guidelines, and has distributed those already, as proposed guidelines, to our hospitals.

The publication in the Federal Register was for the purpose of obtaining comments on these proposals. We did receive comments, about a dozen of them. They came from a variety of people, both within the VA and outside the VA.

We have now considered those in detail and have prepared a second publication for the Federal Register modifying the proposal.

For those of you who have not read the proposals, I would say that they say basically this: that individuals who are exposed to Agent Orange would be judged to have medical conditions that could be -- not necessarily are --

but could be the result of that exposure unless these conditions fell into one of the following categories:

Congenital or developmental conditions. That means the condition in the veteran, not in his children. But if the veteran himself has a developmental condition like spina bifida or sc oliosis, that would not be due to his exposure to Agent Orange.

The second one are the conditions that are known to have pre-existed military service. I think that's self-evident. And third, conditions resulting from trauma, recent broken leg or something of that sort.

Conditions having a specific and well-recognized etiology, like some of the infections or some of the known metabolic diseases, particularly the familial metabolic diseases.

And finally, common conditions having a well-recognized clinical course, such as one-sided inguinal hernia and acute appendicitis.

Now, if there is a condition on which there is doubt, the proposal was that this be decided by the attending physician after consultation with the chief of staff.

In the case of ionizing radiation, whether it was through occupation of Hiroshima or Nagasaki after the bomb or participation in the atmospheric or submarine nuclear tests, the proposal stated that for the purposes of this circular, only cancer would be considered as due to the

ionizing radiation. And, again, the provision was made for consultation.

As as a result of the comments that were received, there have been three changes made in the two circulars, two in the first one. These are some minor changes that are almost editorial, but three are substantive changes.

In the Agent Orange circular, the first change was that we would state the presumption of exposure to Agent Orange by whenever a veteran had served in-country in Vietnam.

This is in line with the VA's policy, as you probably know, in compensation. It has been enunciated in prior publications.

The second change that we made was that in doubtful cases there would be consultation not only with the chief of staff, but with the environmental physician, so that the consultation now was with the two individuals rather than with one.

It left the responsibility in the hands of the staff physician who was taking care of the patient because it is our belief that this individual bears the ultimate responsibility for the care of the patient -- and, therefore, should have the responsibility for making this decision.

The one substantive change in the radiation

proposal was that we would accept the presence of thyroid nodules; that is, nodules in the thyroid as due to exposure to radiation.

It was also proposed that include other thyroid disfunctions; that would be, overfunction or underfunction of the thyroid gland.

The best advice that we could get is that we not include those among the conditions due to the exposures to radiation to which these men were presumed to have been subjected.

The kind of exposure that results in dysfunction generally is either intense ionizing radiation to the neck -- none of that occurred in these trials. or dysfunction is due to the ingestion of reasonably large amounts of radioiodine that results in a general suppression of overall function of the thyroid gland. Again, this is a circumstance that was not envisaged as having occurred during the course of these exposures.

The publication in the Federal Register should be out within a fairly short period. Again, we don't control the time at which the Federal Register publishes our submissions, so we can't give you a precise date for that. But it should appear, I would guess, within the next month or so.

DR. SHEPARD: Thank you. Are there any questions

on the matter of the guidelines on Public Law 97-72?

(No response.)

I might just add that we are working a methodology for tracking the impact of this legislation on our health care facilities.

Specifically, we are putting together a new reporting system which will give us a handle on how many individuals are coming into our medical facilities under the provisions of this legislation.

Incidentally, it will also put in place something that I, for a long time, hoped would happen; and that is, to identify Vietnam veterans as they come into VA hospitals as being Vietnam veterans.

Up until now, that has not been a formal process, and I think we now have at least the first step in establishing that process which should have, hopefully, some other beneficial ramifications.

DR. WOODWARD: Doctor, would that identify them also for out-patient as well as in-patient treatment?

DR. SHEPARD: Yes. The report and the PTF will have indicators as to Vietnam service. And, specifically, not only that, but the results -- if they're admitted, for example, from an out-patient status to an in-patient status, under the provisions of this legislation, that will be indicated.

DR. HOBSON: They will also show, Tom, who has come in claiming exposure in Hiroshima and Nagasaki and who has come in claiming exposure to atmospheric and submarine nuclear tests.

In the discussion here we would welcome comments from any of the people on the panel who might wish to comment on the proposals as they were made.

These were very difficult proposals to write, because, in essence, we were charged with writing a negative proposal, which is not easy to do.

DR. SHEPARD: Any other questions?

(No response.)

MELIOIDOSIS

Also, another item that was not on the agenda that was suggested that we just touch on at least is something that you may have heard about recently, that is the issue of melioidosis and its possible confounding influence on Vietnam veterans.

The suggestion has been made that perhaps some of the complaint symptoms, in fact, illnesses appearing among Vietnam veterans might, indeed, be the result of melioidosis rather than exposure to herbicides or other substances in Vietnam.

For those who are not familiar, let me just give you a very brief explanation of what we're talking about. There is a disease known as melioidosis which is the result

of an infection from a bacterium known as Pseudomonas pseudomallei. This is an organism known to exist in Southeast Asia and in the Orient and, indeed, most of the cases -- early cases of infections with this bacterium were reported out of that geographical area.

There was, indeed, some interest and suggestion that Vietnam veterans returning from Vietnam had some -- or in this group there was some cases of melioidosis.

And I personally remember dealing with that question when I was on active duty in the Navy. I think it's safe to say that although it was looked for because it was kind of a new disease as it affected Americans, at least, I think it's accurate to say that relative few cases were ever turned up, that were documented to be the result of this bacterium.

So -- but in order to get a handle on that, Dr. Custis asked a group of physicians to meet here at Central Office to get some feel for not only the likelihood of this possibility; that is, that melioidosis might, indeed, explain some of the symptoms, and findings being presented by Vietnam veterans, but also to give some guidance in terms of how the VA might deal with this issue.

And Dr. Woodward, whom you'll be hearing from shortly, as well as Dr. Jay Sanford, who is the -- who heads up the Uniform Services University of the Health Sciences.

which Dr. Hodder is a member of the faculty, and Dr. Foege from CDC in Atlanta, and some others did come, and a position paper was developed on the subject.

And for those of you who are interested, we'll be happy to share that with you. But I think the consensus is that it's highly unlikely that melioidosis would be a significant confounding issue in the Agent Orange matter.

Any questions on that subject? Does anybody have anything they'd like to add?

(No response.)

I was not here at the meeting, so I cannot report first-hand, but perhaps Dr. Woodward would like to mention it when he's -- any other questions or comments?

(No response.)

Okay. I'd like now to ask Dr. William Page to bring us up to date on the status of the mortality study which he and his staff have been working very hard at.

Bill?

VA MORTALITY STUDY UPDATE

DR. PAGE: Good morning, doctor.

I anticipate this will be kind of a short report, although that doesn't mean a lot hasn't been going on.

Basically, let me say that the mortality studies have been under review by the Science Panel of the inter-agency Agent Orange Working Group.

A Subcommittee of that Panel was chosen to review in detail the protocol that we submitted to them. They met several times, and in particular, they met yesterday.

At that meeting yesterday, the Subcommittee made some specific recommendations to us. We will be modifying our protocol to incorporate those recommendations into it.

Editorially, let me say that I think yesterday's meeting went very well and I feel that the suggestions and the recommendations of the Subcommittee of the Science Panel were very helpful in doing our study.

So, we're in a position of taking recommendations and incorporating them. Not much else to report on right now.

DR. SHEPARD: Any questions for Dr. Page?

DR. ERICKSON: Can you briefly tell us what the recommendations are?

DR. PAGE: Well, I don't know whether I can briefly tell you what the recommendations are. We've -- one of the questions about the study is how that should be defined.

We have a much better idea of who we're going to be studying. We'll be studying a larger proportion of the deaths than we were originally planning to study under the mortality study, and, yet, we will not -- well, we also discussed the sampling of that. It'll probably be a fairly

simple random sample of Vietnam era veteran deaths. That was the major thrust of what we discussed.

DR. SHEPARD: There was some suggestion on the part of the Subcommittee that we should do a more all-inclusive survey. In other words, identify as many Vietnam veterans as possible and do a -- excuse me -- identify as many veterans who had died in that age group using the BIRLS file and then try and establish, by a hand-search of military records, who, in fact, served in Vietnam and who did not,and then go to the an anlyses of death certificates for cause of death.

We thought that that would be a tremendous undertaking, and have chosen and strongly recommended that we, at least as a first go around, to look at -- to use an automated system -- systems that are available to us, and then proceed from there.

And I think that we now have consensus that that is the appropriate way to go.

Any other questions or comments?

(No response.)

Thank you, Bill.

I'd like now to call on Dr. Theodore Woodward to -- I would like to introduce Dr. Theodore Woodward to this Committee. Many of you know Dr. Woodward. He has a long and distinguished career and is the recent past

Chairman of the Department of Medicine at the University of Maryland. He also has served as Chairman of the Armed Forces Epidemiological Board, and he holds that position at the present time.

His relationship with the Veterans Administration has recently been formalized in that he has now been appointed as a distinguished physician of the Veterans Administration.

And, Dr. Woodward, we are most pleased to have you here this morning and we are looking forward to a cordial relationship in the weeks and months ahead.

ACTIVITIES OF ARMED FORCES EPIDEMIOLOGICAL BOARD

DR. WOODWARD: Thank you.

The reason I'm here is because I recently retired from the Chairmanship of the Department of Medicine. I'm a school teacher, but I'm also a family doctor who makes house calls.

But I think the Veterans Administration found out that I probably exterminated more lice than anybody in the world. And that was in Naples, Italy. I happened to be in charge of the control of typhus in Southern Italy.

The Armed Forces Board is now in its 42nd year. I missed a meeting, and my friends elevated me to the presidency, so one shouldn't miss many meetings.

The AFEB began during World War II, and it was

originally called the Army Epidemiological Board. And then the Virus and Board, and later, the Armed Forces Epidemiological Board.

It serves at the pleasure of the three Surgeons General of the three respective services, and, now, we also serve the Office of the Assistant Secretary of Defense for Health.

I say we serve at their pleasure. We are an advisory board and we have no money.

Originally, there were board members and various commissions; commissions on streptococcal diseases, on meningococcal diseases, on malaria, on epidemiological surveys. We've served for years in helping advise the country on defense against biological warfare and we still do.

The Board has had various distinguished persons with obvious exceptions; but the distinguished as President, Dr. Francis Blake, Dr. John Dingle, Dr. Colin McLeoud, Dr. Gus Dammin.

And these are civilians, such as myself, who take pleasure and considered it a privilege to serve our country in one way or another.

The mission of the Board has broadened considerably from advice on keeping the services healthy with respect to infectious diseases. It has become interested in trauma.

Now, we're interested in health standards. And Dr. Paul Denson, one of the brightest men I've ever known, serves with us, and has developed wonderful guidelines for health standards within the services with respect to obesity and many things.

We're now involved in population forecasting. We're involved in advising in computer methods to devise better plans and techniques for the keeping of the services healthy and for looking ahead.

We're involved in various toxic things: insecticides and disinfectants, etc.

We're now involved in helping the services -- Dr. Hodder and I have been friends for a long time -- of devising new immunization programs for the services, which, of course, would have their affect on the civilian side.

We're concerned with the effects of hyper-immunization. What are the long-term effects of giving too many vaccines. And this relates to the civilian sector as well as to the military, but we serve the military.

So, we're now devising guidelines to help to determine that important issue.

We've become involved with the Navy and the asbestos program.

About eleven or twelve years ago a Board member was asked to visit Vietnam and concern himself with the

effects of herbicides and Agent Orange on birth defects in pregnant women. And I know all about that, because I was the one that went there and never heard a thing about Agent Orange.

But as sort of a ham epidemiologist, I guess, I was able to look into birth defects in Vietnamese women long, long before the United States was involved there. And went into region hospitals and was amazed and delighted to see the wonderful records that existed at the hands of the pediatricians and the obstetricians in Vietnam.

And I was able to determine, at least, on a very gross way, that the incidence of birth defects in Vietnamese women was no different ten years before our involvement or the years of our involvement, but that was a crude survey.

Two or three years ago the Board was asked to become involved in the Agent Orange problem. And we've had Colonel Lathrop report to us on several occasions before and after the National Academy had its input.

We were very impressed with the Ranch Hand proposal -- the Ranch Hand proposal had something to do with some of the revisions and went along -- and the Board went along with keeping the questionnaire as it was delivered confidential.

I had but three days to go over that report. My friends gave me three days to give them some sort of advice,

and I read very slowly. But I was able to get over it, and have to address the matter of confidentiality to myself as well -- the telephone helped me to call some of the great experts on my Board.

I likened the problem to the one which I face when I see a new patient. I don't put a textbook of medicine in front of them and give them a questionnaire of 150 or 200 questions and ask them if they have all of that, because some of my patients are going to have all of that. (Laughter.)

Now, I know very well that a questionnaire which is in the hands of more than two people is not going to be confidential for too long. But at this stage, it did seem to me, as we felt with the Ranch Hand matter, that if that questionnaire could be delivered from person to person on a confidential basis, that might be more appropriate.

But I do recognize the sensitivity of that matter as well as the legal aspects of it and as well as the scientific aspects of it.

And, Dr. Fitzgerald, I am quite sensitive to your comments.

As far as the melioidosis matter was concerned, someone stated not long ago that melioidosis could be a time bomb.

Well, then our newspaper friends picked those things up -- time bombs. Well, tuberculosis is a time bomb.

Food is a time bomb. Smoking is a time bomb. Alcohol is a time bomb.

At the meeting the other day -- you didn't ask me to go on that trip with you down South. (Laughter.)

DR. SHEPARD: I know. I apologize.

DR. WOODWARD: I stayed here and caught a cold. (Laughter.) I think that one of the best things that we could do, and I have advised the Veterans Administration, is to prepare a white paper, to prepare what we in the Army -- I wear olive drab underwear -- a TB Med, we call them in the services, of all the diseases that we have here in the country and have abroad, and state the current knowledge and state the knowledge of whether they're long-term effects, because there are no long-term effects of melioidosis except dying from it, and that's not too long-term. That's like the plague.

So, the best way, I believe, to communicate better with everyone, including our great servicemen, is to communicate in an information way.

Again, I'm here because now I'm privileged to serve veterans in a certain way. And I'm also here as a representative of the Armed Forces Board which is privileged to render any service it can, now and in the future.

And at our meeting, either in July or in the Fall, we will then have a review of the orange -- orange process.

DR. SHEPARD: Thank you.

DR. WOODWARD: Excuse me -- the Ranch Hand process.

DR. SHEPARD: Thank you very much, Dr. Woodward. Are there any questions for Dr. Woodward?

DR. FITZGERALD: Doctor, I'm interested -- well, first of all, let me say that the Veterans Administration used to utilize TB Meds in the late 40's and early 50's and put out some very good ones.

Your suggestion there is quite good, I think, as far as getting information across to the physicians in the VA.

I was interested -- I want to be sure I understood you correctly as far as the exposure of the pregnant female in Vietnam -- did you find that they did not have an increased incidence of --

DR. WOODWARD: Yes. There is a report and I rendered it. I was requested -- the Board was requested to go there by two sources: the Department of State, because something had hit the fan. A two-headed monster had been born of a Vietnamese women, and someone then proposed that maybe it was this herbicide.

And there were several requests for AFEB participation. And Dr. Colin MacLeoud, who would have been much better representative than I, when asked, said, "Ask

Woodward to go." So, he dropped out, and I went, having known nothing about Agent Orange at that time.

But over the weekend I learned something about it at Fort Detrick.

Now, my survey was a very simple one. I'm a very simple person, Dr. FitzGerald. And all I knew to do in a short period of time was to go to the woman's hospital -- I forget the name of it -- in Seoul where a huge number of babies were born --

DR. SHEPARD: Saigon?

DR. WOODWARD: Saigon. Not Seoul. Where did I get Seoul.

And I went into their records. And their records were excellent, better than the records in my hospital in Baltimore, because birth defects of all types were described and well-described. And I was able to go into the records, I forget the number of years, but well before the American participation in Vietnam, as after, and was able to establish that the rates of birth defects were similar before and after and most of those birth defects were harelips and cleft palates.

I then was able to go into some of the regional centers and found good records, and was able to establish that crude relationship -- being no relationship.

And then I visited several of the adolescent and

adult clinics in hospitals in Saigon to determine the crude rate of birth defects in persons of that age, and was amazed to find a number of birth defects.

So, my crude survey, a retrospective crude analysis, showed no increase in birth defects.

DR. FITZGERALD: Thank you.

DR. KEARNEY: Dr. Woodward, did you write this up in any fashion?

DR. WOODWARD: This is written in a report and was submitted to two groups. And frankly, Dr. Kearney, I just moved my office, since I have nothing to do now, but in moving my office, I can't find my copy of that damn report. But I'll find it. (Laughter.)

DR. SHEPARD: Thank you.

Any other questions of Dr. Woodward?

(No response.)

Thank you very much, Dr. Woodward. We really appreciate your being here. I'm sure you'll agree that it's a great asset for us to have Dr. Woodward now in the employ of the VA.

And I have felt for some time, ever since I've had this job, that it is a very natural relationship that the VA should have with the Armed Forces Epidemiological Board, because these dedicated public servants are very /t attuned to what is going on with individuals while in the military.

And it seems very logical to me that the Veterans Administration should keep informed through a variety of ways, not the least of which is contact with the Armed Forces Epidemiological Board. So we will be apprised of situations that may develop or concerns that may be brought to the attention of the Surgeons General and issues that are addressed by the Armed Forces Epidemiological Board, so that when members shift from active duty to veteran status, that we will have some advance notice as to some of the problems that we may be encountering.

And, certainly, Agent Orange has focused on that issue and I think it's very important that the Veterans Administration maintain a close relationship with the Armed Forces Epidemiological Board and, again, I'm so delighted that Dr. Woodward is serving still on that Board, and now can act in a very useful and important fashion, I believe, as a liaison with the VA and the AFEB.

Again, thank you very much, Dr. Woodward. We certainly appreciate your taking time to be here with us today.

I think now we'll take a 15 to 20 minute break. Why don't we reassemble at -- between 5 and 10 past 10:00.

(A brief recess was taken.)

DR. SHEPARD: We begin now with something that I'm looking foward to very much and that is a report from our

friends in the State of Wisconsin, and we're very privileged to have with us today Dr. Henry Anderson, from the Department of Health for the State of Wisconsin; Mr. Donald Laurin, who has been here before and many of you know, I am sure, works in the Department of Veterans Affairs; and, particularly, we're pleased to have Mr. John Moses, who is the Secretary of the Department of Veterans Affairs for the State of Wisconsin. We're delighted to have you with us, gentlemen.

WISCONSIN STATE INITIATIVES

DR. ANDERSON: Thank you. We were here some time ago, but we thought we'd give you a very quick review of the background of our project as well as the state of where we are right now. And I'd like if Mr. Moses would give you a little bit of the background.

MR. MOSES: Thank you, Henry.

The State of Wisconsin operates, and has for many years, the alternative to the bonus idea, the continuing program. We have probably the broadest range of veterans services of any of the state programs.

Until a couple of years ago, we had an outreach program, Vietnam veterans, in the field, contacting and counselling Vietnam veterans with problems and referring them to whatever resources were available to meet those problems.

We became aware of a problem resulting from Agent

Orange exposure, I suppose, late in the game, as is common. During 1980, we proposed to the Legislature that they authorize a special limited term project to identify those Vietnam veterans in Wisconsin who felt that they had been exposed to Agent Orange, and who felt that they had physical ailments that they might have attributed to that exposure.

It was simply an identification project. It was simply to be an informational sort of thing, and, then, hopefully, we would shove them over to the VA for examination as quickly as possible, and perhaps, even to get them to establish -- put in a claim, so that if there were ever to be found causal relationship, they would have their place in line established for compensation.

We proposed to use Department funds, trust funds, which were available for state programs. The Legislature in its wisdom decided that the idea was a good one, that the idea of having trust funds was a good one, but that it would be more appropriate to have the Division of Health in the Department of Health and Social Services manage the program.

The fact that I've been in this job for 20 years and have established some rather warm relationships with some of the members of the Joint Finance Committee didn't hurt in diverting the program from Veterans Affairs to the Division of Health.

In any event, we've worked on a cooperative basis since that time. Our base of information was a collection of reports of separation which we've been working to develop ever since 1962.

The Selective Service copies had been coming to us. We were able to get virtually all of the non-active VA reports of separation among the states and accumulated them.

We have had the County Veterans Service Officers provide us with reports of separation as they are recorded in the County Court Houses upon return of the servicemen.

And because we do have a broad-ranging program that has seen 67,000 small loans, for example, about 100,000 home loans since World War II, mostly in recent years to the young veterans, large numbers of educational grants running to $20,000 a year until the last couple of years, we've accumulated in this third way reports of separation, so that we're satisfied that we have virtually a complete set of reports of separation on veterans, and particularly, Vietnam veterans now living in Wisconsin.

It was with this data base that we were able to develop a tape, test the tape against our income tax records in the states and against the driver's license records for current address, and then provide that to Dr. Anderson and his group for the delivery of the questionnaire to the

returning veterans.

We have something approaching 900,000 reports of separation and this is more than we're credited with having veterans for in Wisconsin.

To give you an idea of the completeness of this base, we are regularly requested to furnish reports of separation to VA installations for establishment of eligibility in -- to the records center in St. Louis, and this sort of inquiry is at the rate of about 3,000 a year or something like that.

So, that we believe we start with a full list of those who served in Vietnam and who are credited and are now living in Wisconsin.

DR. ANDERSON: Thank you, John.

Part of our -- as John said, our main program thrust was, first, to identify specifically Vietnam veterans. And then the second charge, as I'll show you later on the slides, was to provide information, serve as a central information source, to the veterans who had concerns, and, at least in the earlier years, or two years ago, two and a half years ago, really didn't know where to call, who they could go to.

We're reading a great deal in the press. News on the television. Concern that local physicians didn't know how to advise, and frequently, local groups didn't, so we

were supposed to set up a central information source readily available to the individuals as well as the many diverse groups.

And I'd like Don Laurin, who was and is our sole staff on this project, to give you a little background on his experience in the last two years of this project.

MR. LAURIN: I'd just like to say on behalf of the great State of Wisconsin and its 60,000 plus Vietnam veterans, I would like to thank the Veterans Administration and this Counsel for the opportunity to be here and speak today.

For the last two years, Wisconsin has been actively working on the Agent Orange issue. We have sought to identify those Vietnam veterans who believe that they were exposed while in Vietnam and to try to determine the extent of their health problems.

Dr. Anderson, very briefly -- in a short time will discuss that part of the program. And I'm sure that the information he's going to present to you will be of interest.

Another aspect of our program has been to try and persuade veterans to be examined by the Veterans Administration. We now estimate that approximately 5 to 7 percent of our veterans have been examined.

This figure to me is quite discouraging simply

because approximately -- over 15 percent of the veterans who have returned our survey indicate that they feel that they were exposed. Another 66 percent are unsure.

So, we have a long way to go before we get every veteran in for an examination.

Our plan is to target those veterans who think they were exposed and the veterans who were unsure and strongly urge them to be examined.

And in order to facilitate this, next month we will be sending out a mailing of over 30,000 to the veterans telling them that if they think they were exposed, or if they're unsure, or if they're having health problems to get into the VA and file a claim.

In addition to doing this, we're also going to be producing a public service announcement which will be aired state-wide some time in May or June, and this will also urge veterans to get an examination.

Our goal for the remainder of the current Fiscal Year and for most of 1982 and '83 Fiscal Years will be to have every veteran who is concerned for his health problems examined.

To date, we are glad that we have had excellent cooperation with the Veterans Administration and hope that this cooperation between our two agencies will continue, not only for the benefit for those of us who are working on

the issue, but especially for those veterans who look to us for information and guidance on a very emotional issue.

We're also very pleased to have learned that recently the Veterans Administration Hospital in Milwaukee is conducting over 80 Agent Orange exams per week.

But at this rate, it will be a very long time before all of the veterans are examined.

Before I turn the floor over to Dr. Anderson, I would simply like to commend the Air Force on the way that their Ranch Hand Study has been going.

According to one of Wisconsin's Ranch Handers, the examination was the best that he has ever had.

Thank you.

DR. ANDERSON: Thank you, Don. Through the DD-214 discharge papers, we identified 58,360 Vietnam veterans. In addition to that, there's 130,000 Vietnam era veterans.

Unfortunately, to date, because the project was specifically targetted to Vietnam veterans, the records that we have computerized for the addresses, as well as additional information on when they served, branch of service, MOS and the other information on the DD-214's, we only have that computer listing for the Vietnam veterans.

The other 130,000, as John can tell you, are sitting in boxes in the basement of the Veterans Secretary's

office.

MR. MOSES: I think I should add that the question of confidentiality on these records has been a sticky one to us.

And at times, between our two agencies in Wisconsin, it has developed into some rather strong discussions.

We incorporated into the computer tape all of the detail that Dr. Anderson felt was necessary including the MOS. We, however, have retained the tapes and they remain in the property -- in the possession of the Department of Veterans Affairs.

We handled the mailing, so that only when a veteran who has received the inquiry mailed out through our computer section responds does the individual named, the identification, become possible. And that is considered as a voluntary act on the veteran's part consistent with our charge to retain the confidentiality of the information.

DR. ANDERSON: So, with the questionnaire that we mailed out -- let me start here. I think we could turn the lights off a bit.

(Showing of viewgraph.)

The main objectives of the project as it began are listed here. The first thing we needed to do was to identify all of Wisconsin's Vietnam veterans. The second

was to find an easily accessible mechanism for the individual veterans to have their concerns listened to and addressed.

(Change of viewgraph.)

This we handled through the development of a 800 toll free phone number with a 24-hour answering service and individual return of calls, or individual answering by Don during the daytime hours.

We also wanted to establish contact. The local veterans were telling us that they needed some central area. They wanted to participate. They were feeling that they were no longer in control of what was going on. Things were passing them by.

And, so, one way we thought to get all of the veterans involved and, hopefully, continued participation and involvement, was through the development of a perception of exposure type questionnaire.

I would say at this point that just as you heard previously the concerns that the VA has about their examination and how that does not represent an epidemiological study, this also in no way should be considered to be an epidemiological study.

All the information that we've gathered is strictly the perception of the individual. In other words, his interpretation of the questions as well as his interpretation of his health concerns and whether or not he thinks

he was exposed.

At this point in time, we have no verification of the information other than we do know from the discharge papers what branch of service and when he was in the service and in Vietnam. So we have been able to cross-check that data, that they were in fact there and what branch of service they were in.

(Change of viewgraph.)

We then went on to develop multi-media educational materials to give the veterans information on where to go, who they could contact, what they needed to do to file claims, to get in touch with their County Veterans Service Officer and through that mechanism be channeled into the system.

We also, as Barclay can tell you, some time ago worked with the educational TV people in Madison and developed a one-hour panel discussion with Barclay and a number of others on that, which was there throughout the state -- to also reach and bring some of the issues and the scientific aspect of the discussions to everyone.

Probably the biggest job, the most difficult to do, but we've been so far quite successful at, and Don didn't mention it, but as I'm sure you're all aware, there are many, many groups in the country, in individual states, they even have perhaps a closer contact with all of them --

and now, like Wisconsin, many other states are developing programs -- even at the county level, there are task force groups put together to review what information is available and try to establish programs, and we felt there was a definite need to have some central group at the state level coordinate these activities, act as a contact with the Federal programs, both -- so that there would be good communication as well as accurate communication and interpretation.

(Change of viewgraph.)

The next -- the last is what I'll show -- we have now -- and that's also to ascertain the extent and priority of health problems perceived by the veterans.

Our approach is perhaps somewhat simplistic, but we felt the first thing we needed to know is, on a large group, state-wide, from a public health standpoint, the perception of illnesses perhaps equally as important as the actual prevalence of specific problems.

So, we felt that we would be able to, on -- in a cost-effective way, obtain the perceptions of health and then target populations to get them into a physician to either change their perception of what their problems or start receiving some therapy to alleviate their concerns.

(Change of viewgraph.)

This, I hope you will recognize, the State of

Wisconsin, with many little tiny numbers. And I only have a few slides with lots of numbers. But this just shows all counties of the state, the upper number with a T after it is the total number from the DD-214's, the 58,000 individuals, how many are in each county; the percentages below are the response rates.

And you can see that we did have responders from all counties. Some counties, as you'll see, had -- like the Mennominie Indian Reservation, there was a total of 19 Vietnam veterans. That was our low response rate at 42 percent.

But again, with only 19 individuals out of 58,000 you can see most of them are in a higher range.

(Change of viewgraph.)

This shows you the percent response range of each of the counties. Down below you can see we did much better within the State of Wisconsin. This includes both permanent and current addresses after the computer runs and cross-checks of the 58,000.

There remains some 12,000 for which we could not get a current address. We went then and used as a mailing address, their discharge address listed on the form, which frequently was a parent or someone else, and sometimes 10 to 12 years old, but we used that to mail out, and you can see the low number on the bottom there, the 6,000

individuals had very poor addresses, and we did get 14 percent back. But, of course, that would be a group that probably very few of them, in actuality, received the questionnaire.

(Change of viewgraphs.)

This shows the age distribution of -- the red is the total population. The green are our respondents, and you can see that we have -- quite representative, at least, as far as age distribution, a response to our questionnaire.

We're perhaps slightly overrepresented in the 33 to 37 year old group, and some of them underrepresented in the over 43 group.

Again, we have to recognize that we do have a total cohort and at this point, we do not know how many of them would be deceased, but we would expect that the majority, of course, would be expected to be in the older age group. This is the age as of their birth date in 1980.

(Change of viewgraph.)

This shows the distribution, again, of all veterans in red by branch of service, the branch across the bottom. The green is our respondents.

As you might expect, we had a little bit better response from individuals from the Army and an under-response of a few percent amongst the Navy personnel.

(Change of viewgraph.)

This shows you the various demographic characteristics. As you'd expect the distribution of the sexes, virtually all were males. Only several hundred females, which may be a special group at some point to further investigate -- however, our responses are just to the males at this point in time.

Representing Wisconsin's racial distribution -- as you can see, 97 percent of the respondents were white. According to the 1970 census, listing veterans, we could have expected there to be about two percent blacks. So, we're probably somewhat underrepresentative of Wisconsin veterans in the state.

But, again, overwhelmingly, it would be expected that in the State of Wisconsin, there would be primarily whites.

You can see 79 percent reported to be currently married. Nine percent divorced, eleven percent still remain single.

One interesting factor which -- from the epidemiologic standpoint -- begins to throw a few concerns into trying to establish where a man was -- the fact was that in our group of respondents nearly 20 percent, or one-fifth, had multiple tours of duty, frequently in different sectors of Vietnam.

As Don said, again, this is somewhat out of date

as we have not yet been able to update the individuals who have come in for exam during this last year. So, when we say four percent were examined, that is prior to January, 1981.

(Change of viewgraph.)

This shows the current age of the respondents by branch of service. And as you can see, unlike the overall age distribution, comparing the two -- the overall population and respondent population -- there's somewhat more discrepancy in the ages by branch of service, with the Marines and Army being somewhat younger than the Air Force and Navy personnel.

(Change of viewgraph.)

This shows the distribution of respondents by months of service in Vietnam. Again, the predominant group, 7 to 12 months, and most of those being in the 11 month tour of duty.

(Change of viewgraph.)

This just shows the similar type of breakdown by branch of service. Again, there are considerable differences between the length of the tour of duty by branch of service.

Most of the Navy personnel that were there in the one to six month -- would have been territorial waters, individuals who had shorter cruise periods in the area and

that seems to be reflected in what they have told us of when they were in Vietnam or the Vietnam environs.

(Change viewgraph.)

This shows the distribution of respondents by the first year they went -- were sent to Vietnam. You see very few -- two to three percent -- stated that they first started their tour of duty prior to 1964.

Just as would be expected, the majority of individuals in the '65 to 1972 period, a few reported to us that they didn't enter the area until '73 or later. Again, that's a very low percent.

(Change of viewgraph.)

This just shows, again, the breakdown by branch of service. As you can see, the Navy personnel reported that they were there in the earlier years, predominantly in territorial waters.

Again, you can now -- as our computer prints on our slides, begin to see a small blip over there in the '73 to '76 -- again, predominantly in the Navy personnel.

(Change of viewgraph.)

Now, this is -- one of the questions we asked was whether they thought they might have been exposed to Agent Orange. We did leave a little space for them to write comments as to when, where and how, because of the need to have a very short, brief form, we kept it -- kept their

comments in a free format, but we did computerize all that, so we do have, for each individual, a little statement, if they chose to give us one as to when they felt they were exposed, their explanation for that -- so, here you can see the Army, with roughly 17 percent feeling that they felt they could say they were exposed; Marines a little bit higher than that; and, as you might expect, the Air Force and Navy personnel somewhat lower.

(Change of viewgraph.)

Now, we also asked them about their perception of their health. We grouped it very broadly. Rather than giving them a long list of illnesses, we asked them to indicate by organ systems, whether they had a problem or not currently being treated or have they seen a physician for it.

This one is a breakdown of their perceived exposure -- I'm one slide ahead of myself here.

This shows, for the Army, by the various Corps areas, whether or not they felt they were exposed. From some of the information that we have, it appears, at least what is out in the press and reaching the veterans, that the most heavily sprayed areas were I Corps, which is the one on the far left and III Corps, which is the third and, in fact, for the Army personnel, this is the breakdown.

We can do the same thing with the Marines, except

virtually all of our Marines served in I Corps.

(Change of viewgraph.)

We also asked them to identify how they felt they might have been exposed. And as you'd expect, most of them felt they might have been exposed as infantry, passing through sprayed areas.

You can see that a smaller percentage felt that they might have been exposed either by virtue of being a pilot or a crew member.

We also asked a broader question whether they might have been -- although the project began with an emphasis on Agent Orange, we felt that it was very difficult to determine whether to be concerned solely about Agent Orange. We are interested in all possible exposures to chemicals. And, in fact, the mixer categories, I can't give you all of the two by two tables and multiple interactions, but, in fact, amongst this three percent who said they may have been exposed as mixers, only about a third said they may have been -- they were -- they definitely felt they were exposed to Agent Orange.

But the mixers handled many different chemicals, so this was not solely that they felt -- or these groups as you see the precentages here -- felt they were definitely exposed to Agent Orange, this was just the type of job they did.

But they may have come in contact with -- the applicator groups was primarily -- had to concatenate it a little bit. But it was ground application, backpacks, or along the rivers where the applicators -- in the definition we gave them to deal with.

(Change of viewgraph.)

Now, we come to my perceived health problem list. What we did, just to give you a summary picture, is we summed across the eight possible variables. And as you can see, 73 percent overall of the 28,000 respondents did not report that they had any current medical complaint, at least they did not report it as such on our form, which we felt was a very interesting and important figure to recognize that, in fact, the majority of our -- the majority of our respondents currently felt they were in good health.

And, of course, that is their perception of their health and we don't know how many of them may have hypertension or other diseases. So, we are encouraging them all to be seen by a physician.

But at least their perception at this point in time -- the majority of them have no problems. And you can see, as you'd expect, the fairly nice follow-up. About 13 percent had one perceived health problem area, and again, two, three four, and a very small number of four

or more.

(Change of viewgraph.)

There's the breakdown by branch of service, and you can see that the Navy and Air Force personnel -- or the Navy personnel, 80 percent of them, reported having no health problems versus 63 percent of the Marines.

And, again, you can see the -- as you go out one, two and three -- that the Army and the Marines consistently have the highest percentage of multiple health complaints.

(Change of viewgraph.)

Here are the specific symptom areas. As you can see, overall, 10 percent are reported that they have a current skin problem. Ten percent reported a current stomach problem, eight percent brain, nerve problems, chronic pain was one of the things that our review panel that -- as every survey has to have a review panel -- the veterans who reviewed our questionnaire felt that we ought to include as a separate category chronic pain, which we did and that came out fourth highest. And we can see reproductive, liver -- and about a half a percent, interestingly similar to the percentage in the VA examinations, reported having experienced or are currently being treated for cancer.

(Change of viewgraph.)

This shows the breakdown of the specific -- four of the specific health related areas by branch of service. Again, listed, as I showed you, the perception of exposure.

The same groups that had the high perception of exposure had a high perception of difficulty. Marines and Army counting for the vast majority of these complaints, until you see -- you get out to heart and lung. There the branches are quite similar.

The other four that I didn't choose to make a slide into are very similar in their distribution to the heart and lung. The three that stood out as showing discrete difference between branches were the skin, nerves and stomach. Of course, those were the three most widely publicized complaints.

(Change of viewgraph.)

Here, as you might expect, we have the same perceived health problems. In here is the percentage of individuals who feel they were exposed, whether they were uncertain whether they were exposed or not, or who definitely felt they were not, and the proportion of each of those groups who had the type of complaint.

You can see here amongst the people who felt they were definitely exposed 25 percent of them had skin problems, about 22 - 23 percent brain and nerve.

And you can see those who said they felt they

were definitely not exposed, consistently had very, very low levels of health related complaints.

(Change of viewgraph.)

This is looking at it the other way around, looking at the groups who either have the health complaint, which is the red group, and the green group is those who said they did not have a health complaint, in whether or not these different groups felt they had been exposed.

You can see if you look at the small groups of people who have the health complaints, then it becomes much more dramatic how many of them also report that they think they were exposed.

That's why I say you have to keep in mind perception here. We have no causality. We don't know which came first, whether they felt they were exposed and then developed the problem, or whether they developed a problem and then began a more concentrated effort to try to recall whether or not they might have been exposed.

(Change of viewgraph.)

This is -- you've seen this slide again, but I just wanted to remind you to see the difference here overall in by-branch -- specifically skin -- to see the considerable differences in the overall prevalence in the group.

(Change of viewgraph.)

Where we look at this slide -- where we look by

branch of service, this is just for perceived skin problems, and break them down by the three categories that the people put themselves in, you can see, although a very overall small proportion of Navy personnel and Air Force personnel had skin problems, those individuals who felt they were exposed accounted for those -- really there's no difference between the branches when you look in the -- whether or not they think they might have been exposed.

(Change of viewgraph.)

Now, since it came up this morning, I thought we would show you a few slides on our respondents in the various breakdowns of people who reported having been in for an Agent Orange exam at the VA.

Here you can see the breakdown by branch of service. You begin to see that all these slides look similar with the Marines topping the list on all of these slides, the Army next and the Air Force.

Interestingly, quite a number of our Navy personnel have also been in.

(Change of viewgraph.)

This is, as you might expect, in that you're concerned about the -- having some estimate of whether or not those who are coming in are representative of the overall group, this slide and the next one will show you that they are not.

As you can see, those who think they were exposed 14 percent of them have been in, which is, perhaps, from the Agent Orange perspective, more encouraging as the individuals certainly have -- feel they were exposed have taken advantage of the program.

As you can see, less than one percent of the group who don't feel they were exposed have been in.

(Change in viewgraph.)

If we look at it another way by multiple symptoms, as you might expect, the more symptoms you have the more likely you are to have taken advantage of the examination program -- are those who, as you will recall -- that 73 percent of the people are in the norm group and less than 1 percent of that group have been in for exams versus those, I think, 36 individuals with six or more complaints. Thirty-eight percent of them have, in fact, been in for an Agent Orange exam.

(Change of viewgraph.)

We also asked the individuals whether or not they were receiving disability. Again, remember, these, of course, are not Agent Orange related disabilities, but any service related disability.

Here is the breakdown by branch of service: Marines, Army, Air Force, Navy in that order.

(Change of viewgraph.)

If we look -- using the scale that proceeds multiple health problems, you can see the more reported health problems the more likely they are to be receiving some form of disability.

So, I think you can begin to see the complexity faced by the epidemiological studies -- they are going to have to sort out people -- as we can see from the previous slide, a fair proportion of those who may have been exposed also may have a disability which could be accounting for some of their symptomatology.

And we do need to -- rather than look at fairly simplistic slides like this, when we have validated, verified information, begin to look at the multiple factor interactions of the number.

Ten to twelve years have gone on since the exposures and many environmental occupational factors may also be accounting for some of the concerns.

(Change of viewgraph.)

So, at this point in time, we feel we do have some identified prospective needs, at least as we're hearing them on the firing line at the state level. Hopefully we are successfully relaying them to the Federal level.

But there clearly is a need for clearing house educational programs, central information to rapidly disseminate to the very varied groups who need to know and

have that information.

We need to have a better means of identifying possible exposure. As you can see, there are many explanations for what you saw on these perception slides. But clearly you can't make a causal -- and we do need to have an objective measure -- it could as easily explain our findings that individuals who have a problem have identified a possible exposure at a higher rate than those who have not thought as much about it.

So, we do have to have an objective measure and then -- it seems that even though it's to be held secret, it has been a possibility where there's great concern by the veterans who felt it certainly ought to be possible than at first when it came out that it would not be possible.

Then, number three, which is, of course, already going on, but the veterans in Wisconsin are telling us that they would like to see a detailed characterization of mortality and morbidity on more than just a perception -- of course, this is a much more costly, larger scale procedure than the current perception type of evaluation, requiring much more validation checking.

We need to identify all the other risk factors. We did get smoking histories; just to keep our presentation within some time constraints, we didn't show you some of

those, but we did try to identify a few risk factors.

There also is a need to address concerns apart from Agent Orange; most specifically, post-traumatic stress reaction and counselling to the veterans at the local level.

That should do it.

DR. SHEPARD: Are there any questions for our friends from Wisconsin?

(No response.)

And we are going to meet with you this afternoon?

DR. ANDERSON: Yes.

DR. SHEPARD: Great. I look forward to that.

We'd now like to open up the discussion to representatives from service organizations, if they would like to bring any concerns to the group.

And I'd like to first call on Dr. FitzGerald.

REPORTS FROM VETERANS SERVICE ORGANIZATIONS

DR. FITZGERALD: Just as a matter of information, the monthly American Legion magazine has had a series of three articles concerning Agent Orange, the last of which will be in the March issue, which I think have been fairly well done and very accurately portrayed.

This means -- I think it could also be utilized as you come out with statistical information as a means of getting across to the veterans, which, again, was brought

out in the Wisconsin group, their sincere need for some reassurance as to these dangers that have been portrayed in the media and what our actual findings are now that this time passes.

The three articles in the Legion magazine will be collated and put in a single form if you so desire.

DR. SHEPARD: That would be great. Yes, I would commend the Legion on these articles. I think they're very, very helpful and we found them very interesting and commend you on your efforts.

Unfortunately, Mr. Furst, Jon Furst, could not be with us today. We fully expected that he would be here, but late yesterday afternoon he called, and for reasons that are unclear to us, was not able to be with us today.

I'll try and reach him some time in the next day or two to find out if he had any material that he wanted to share with the group and diseminate/s it to you.

Next, we'd like to call on Mr. Fred Mullen.

MR. MULLEN: Thank you very much.

I'd like to first address the issue of melioidosis and make reference about Dr. Hodder's comments regarding the French population.

And certainly we have our own population that -- I believe the National Academy of Sciences is following roughly 700 Vietnam POW's. They would be more likely to

/1

have been exposed to the Pseudomonas pseudomalei than the general population of Vietnam veterans.

And I think if there was a problem along this line, NAS would have recognized it by this time. I think that we ought to put a lid on that as quickly as possible to avoid another media blitz and burdening the Vietnam veteran with what -- "what have they done to me now?"

And we don't want to perpetuate this type of thing, and I think it ought to besquelched as quickly as possible, because I don't think it has any merit whatsoever.

Certainly, we have made recommendations to Mr. Nimmo along these lines and various other researches that we have conducted into this area have shown that even some of those may not have been truely adequate recommendations, but given the time that -- the lapse between our meeting with the representatives who brought up this position and the -- our recognizition of the immediacy of responding to this to the Administration, we weren't able to research it as much in depth as we would like to have done.

Again, I hate to bring this up, and I will refer to Dr. Hodder's comments regarding the reverse bias that may be caused by the secrecy of the questionnaire, examination, documentation collecting and I only have one other question and that is I understand that the 38 proposals for further studies that were solicited and received from 31 of the 172

medical centers will be looked into by our merit review panel.

My question in this area is of those 38 proposals was the question that resulted in receiving these proposals -- do you feel further study into the area of Agent Orange is necessary, or into herbicides, and, if so, do you have any breakdown of which proposals were received requesting or confirming the need for investigation into a particular herbicide, rather than just Agent Orange?

MR. LEVOIS: I think he's responding to a section of that memo, and, so, I'll answer him.

The proposals aren't in yet. There's a deadline of April 15th for the proposals to be submitted. What we received were feelers, concept papers, things that were not scientific protocols.

They're undergoing a process right of development. We don't know exactly what we will receive, although we do have a breakdown of what we were felt out about and they were responding to dioxin effects.

And they were -- many of them were very detailed clinical examinations of particular sites and particular animal species and this sort of thing, looking at a wide variety of problems.

Animals were not the only systems being evaluated. There were some human studies as well. And they're all

receiving attention of their principal investigators at this time, but we just don't know where they are.

MR. MULLEN: Well, if I remember correctly, this was initiated two months ago -- at the last meeting, I'm sorry -- under the auspices of Dr. Hobson and Dr. Kinnard.

And is this the same study that was supposed to go out, I believe -- other herbicides as well were mentioned at that point, not just dioxin containing herbicides.

Now, what I'm hearing from you is that the question was in regard in to dioxin only -- or are these responses in regard to dioxin only. And if these are in response of dioxin only, were there other responses that concerned other herbicides?

DR. SHEPARD: If I may, I don't think we restricted the research efforts to Agent Orange or even dioxin. I think it was a broad solicitation.

And I see Dr. Kinnard is here. Perhaps -- he's most closely involved in this effort. Maybe Matt could bring us up to date.

DR. KINNARD: Good morning.

I have before me the Twix circular that went out on or about January 15th, which requested for all VA medical specific centers to respond to a question regarding their interest in participating in the Agent Orange/Agent Blue Research program.

The question is stated in this manner: "This

circular, 10-82-3, effective January 15th, 1982, Subject: Information for Special Solicitation for Research Proposals Dealing with Agents Orange and Blue.

FROM: VACO Director, Medical Research Service. List all programs to be submitted under this special solicitation and list all programs involving Agents Orange and/or Agent Blue being submitted for regular merit review on the April 15th, 1982, deadline.

Name of the principal investigator and title of program.

This information must arrive in VACO by January 20th.

Now, we're not being very rigid about the 20th, as "the" deadline because I think that date was given for a specific reporting. But any responses that we have receive after the 20th will be identically reviewed, as those having been received by the 20th deadline.

But to answer your question, Mr. Mullen, the survey for investigator names and titles was for both Agent Orange and Agent Blue, which is what our initial solicitation letter asked for back in August.

MR. MULLEN: In that regard, the solicitation, as I understood it there, was and/or. The question is how many -- how many solicitations have resulted in requests for or recognition and need for a study into Agent Blue, how many into Agent Orange and how many for both herbicides?

DR. KINNARD: I'll give you an overall figure. As of yesterday, I did a tabulation. There had been 46 titles submitted. And my best guestimate is about five or six of those were for Agent Blue and the remainder for Agent Orange.

MR. MULLEN: But there was no title for both.

DR. KINNARD: I don't think so. As I recall, they proposed to investigate one or the other herbicide.

MR. MULLEN: Well, see, my question was -- this morning I got to number 38 from 31 medical centers, and now here we're talking --

DR. KINNARD: In some medical centers there are more than one investigator, so --

MR. MULLEN: Oh, I see. Okay. But I don't understand this 46 figure.

DR. KINNARD: This is a new figure.

MR. MULLEN: Okay, thank you. That answers my question.

DR. SHEPARD: Any other questions on the matter of the research efforts?

(No response.)

Unfortunately, Mr. Charles Thompson had to leave. Their organization is having a series of meetings today and he was not able to stay for the remainder of the program.

He did tell me that they reviewed the guidelines.

We asked that the members of the Committee comment on the guidelines, and they apparently did not have any specific comments on the guidelines, and I infer from that they were in general agreement with the guidelines, so I think we have the report of his organization in that regard.

We'd now like to open up the meeting to questions from members of the audience.

COMMENTS AND DISCUSSION

DR. SHEPARD: We have a question from John Terzano of Vietnam Veterans of America. His question is: Is the VA going to recommend expansion of the epidemiological study to service in Vietnam?

This question has come up on a number of occasions, both here and in Congress, and in correspondence, and it may merit a word or two.

I think as the epidemiological study protocol is evolving, it appears that the cohorts to be studied will include a group of veterans who had a high likelihood of exposure in Vietnam.

Another group of veterans who served in Vietnam but had a low likelihood or no likelihood of exposure and another group who did not serve in Vietnam -- it appears that something along those lines will develop.

And, so, I think that it's quite clear that there will be an opportunity to compare service in Vietnam with

veterans of the Vietnam era who did not serve in Vietnam so that one can make, I think -- will be able to make some observations on the basis of that comparison.

Now, this issue of expansion of the study becomes somewhat ambiguous, because in the minds of some people, I believe, it's been recommended that the study be expanded to include other specific exposures.

To date we have not developed any plans for studying other specific exposures other than Agent Orange.

Of necessity, other exposures will be included, because I don't believe that there's any way that we can separate out other exposures other than in the Ranch Hand Study which will probably come as close to that as possible.

And when I say other exposures, I include other chemicals, herbicides, insecticides, prophylactic medication, so forth.

So, I don't think there's any realistically scientific way in which we can tease out each of the various exposures and study them as an individual exposure.

So, I don't know if I'm answering your question, John, but I did want to make that point. I think of necessity it will include the opportunity to look at Vietnam service in its entirety. And hopefully we will be able to identify exposed cohorts. We'll be able to take a

look at the Agent Orange issue.

Now, this is a question for Mr. LeVois: Could you explain the distinction between the VA mortality study and the mortality study included in the epidemiological study.

MR. LEVOIS: Sure. The -- by virtue of the fact that we're drawing large cohorts, some people in the epi study will have died, and we will be able to go back to the cause of death re cords and identify what they died from.

That would constitute a small mortality study, but it would probably be very small, because we're starting out with living people, a small fraction of young men would have died by now. And it probably would not tell us a great deal more than we would learn -- or anything more. It wouldn't tell us as much as we would learn by doing a full-scale mortality study separate from the epidemiological study.

That's why we're planning on doing a separate study. The mortality study that we're planning will help us to identify certain types of diseases that are lethal. Because by definition, a mortality study -- the people have died.

We will start with the BIRLS tapes which will identify deceased veterans. We will go ahead and do matches

which will allow us to identify Vietnam -- non-Vietnam deceased veterans, and we'll have to get cause of death on those groups -- and do a proportional mortality study comparing cause of death of service in Vietnam and service outside of Vietnam.

Yes?

MR. WILSON: You mentioned the BIRLS tapes. If I'm not mistaken, I read something from the General Accounting Office, the November 18th hearings, that took -- indicated that there may be a problem with these BIRLS tapes. They may not, in fact, provide reliable data.

MR. LEVOIS: Our most recent evaluation of the BIRLS tapes is that they're 95 percent accurate. In other words, they're 95 percent complete in terms of the event of death being recorded.

And you could -- correct me if I'm wrong -- but I believe that the National Academy of Sciences validates our process of recording the location of the stored record of death, and that that was 95 percent accurate. Is that correct?

DR. SHEPARD: Maybe I can amplify on that a little bit.

There is an automated BIRLS file. And then there was, at least, a less automated file, I believe. Some time ago the National Academy of Science evaluated the accuracy

of the earlier file and determined that that was 95 percent accurate on the point -- or 95 percent complete on the fact of death.

The National Academy of Sciences is now doing a second validation study on the automated BIRLS file. And that is currently in process. We don't have any reason to suspect that it will be any less complete or less accurate.

MR. LEVOIS: I don't think I finished with the -- the tie-up between the mortality study and the epi study -- there was some discussion earlier about the usefulness of using mortality information to help fine tune the epi study -- it really is not quite that clear cut, because the epidemiological study is going to be looking for morbidity unless the mortality study uncovers processes that lead to death that are very slow and drawn out, but can also be diagnosed with a fair degree of accuracy.

It really will not provide a great deal of fine tuning of the epi study. We need to have some idea of what we're looking for and go ahead and do an epi study.

A mortality study is quite separate. It's a useful study, it identifies lethal sorts of things and things that act within the 12 to 18 years that the disease process has been allowed to proceed since service in Vietnam.

But that could be a different class of illnesses

entirely than what we will find in the epi study if we find something.

So, they're really two useful and separate studies that we're doing and not intimately related to one another.

DR. SHEPARD: Thank you.

There's a question for Dr. Hobson from the same person, Katy Burdick, from the Senate Veterans' Affairs Committee Staff: Is hypofunction of the thyroid gland being considered one of the disfunctions excluded under the revised guidelines for implementation of the health care provision of Public Law 97-72?

DR. HOBSON: There is no specific exclusion.

All we did was to exclude it from a condition that would almost automatically be accepted.

Any of the conditions that are presented can be considered. Most of them, I think, probably would be pretty farfetched. For example, digestive disorders at this stage of the life of the individual who was exposed during the 50's and before would be pretty hard to attribute to radioactive effects.

It is also extremely unlikely, in the opinion of most experts, that hypofunction of the thyroid would come from the kind of exposure that these individuals had. Although very unlikely, it's not excluded, but it's not automatically accepted either.

DR. SHEPARD: There's another question directed to me: Since you will be identifying Vietnam veterans as such when they present themselves at VA medical centers for care, will you use this flag to identify specimens and slides which should be sent to the AFIP as part of the Tumor Registry Review?

Yes. That was one of the motivating factors to set up that flagging system so that we could have a way of getting to the VA medical -- so the VA medical centers themselves would have an easy identifier on which to send specimens to the AFIP.

So, that certainly will be one of the beneficial spin-offs I referred to earlier.

Those are all of the prepared questions that have been submitted to us. Are there any questions from the floor? We have some time to take those now if you'd like. Don?

MR. LAURIN: I had a number of Vietnam veterans in Wisconsin ask me what is happening with the tissue bank. In other words, some veterans have had biopsies taken and they have not gotten word back as yet as to what's been going on with that. And they wonder whether or not they're going to get a response from the VA about that biopsy.

DR. SHEPARD: Are you talking about the fat biopsy study or are you talking about the AFIP Registry?

MR. LAURIN: The Registry.

DR. SHEPARD: The AFIP Registry?

MR. LAURIN: Yes.

DR. SHEPARD: There was not a system in place to give them the results of those biopsies. And it's my -- I would be surprised if those biopsies were done for any specific reason other than to look at the Agent Orange issue.

The AFIP Registry is composed of tissues that are submitted to the AFIP on Vietnam veterans who were having surgery and on whom autopsies were performed in order to establish a registry of tissues on Vietnam veterans, to see if any disease patterns are emerging.

If the veterans are concerned that they're not getting the answers back, then they should contact the Veterans Administration hospital where that biopsy was done in order to get the result of the tissue examination.

We can provide information on what -- and will and have in the past provided information on what has been submitted to us from the AFIP in terms of the analyses of the tissues that are being submitted to them in an aggregated form.

But in terms of getting a specific -- answering a specific veteran's question about his specific biopsy, that would more appropriately be done by contacting the Veterans Administration hospital where that was done.

Now, as one of the services that AFIP provides to any pathologist who submits tissue, a report of AFIP's diagnosis of that tissue is sent back to the hospital submitting the tissue.

AFIP does not provide that information directly to the individual on whom the specimen is performed and the family of whom the autopsy was performed.

So, they act as a consulting group to the medical institution submitting the tissue.

MR. LAURIN: One more question, please.

DR. SHEPARD: Yes.

MR. LAURIN: And that is we had veterans who served in Vietnam before, in 1964; they tell me they're not considered Vietnam veterans for benefits. And they're wondering whether or not they can get their Agent Orange exam and then receive benefits for service-connected disability if they're not considered to be a Vietnam veteran.

DR. SHEPARD: Let me answer -- we have not placed any restriction on Vietnam veterans getting into the Agent Orange registry or having an Agent Orange examination.

So, there's no time limitation on that. As to the legalities of whether or not they are considered Vietnam veterans, I would have to -- I'm not aware of any. Fred?

MR. MULLEN: Yes, sir.

The actual period of war was from August 5th, 1964,

to May 7th, 1975. Ranch Hand began in '62. So, they are considered -- anybody before August '64 is considered peace-time service, but if they have a disability that can be related to that exposure, then certainly they can get it service-connected. There's no problem there.

The only problem there would be is if it's a non-service-connected disability and they had peace-time service. They would not ordinarily be eligible for pension, or someone during a peace-time era with less than 180 days. But as far as service-connected, there's no problem there.

DR. SHEPARD: Yes, that was my impression that service-connection determinations have no regard to whether or not a person served in time of combat per se. Simply having been on active duty is the determinant there.

Yes, John?

MR. TERZANO: Could you give me a timetable at all on the epidemiological study? I know OTA met earlier this month and their comments will be due in a couple weeks. You're reviewing it now and the Science Panel is reviewing it.

When is UCLA going to get the comments back and do the revisions that are necessary?

DR. SHEPARD: I would hope that if we get the comments back from this Committee within the next three weeks, and the other Committee comments should be forwarded --

the contract calls for UCLA to have 30 days in which to make their final submission, prepare their final submission following the formal submission of the review comments to that group.

So, I would say within two months we should have a final product. Hopefully, if everybody stays well.

MR. LEVOIS: We should mention that we would like very much to use the National Academy of Sciences as a reviewer also.

The National Academy of Sciences cannot be moved along. We have a contract with them. We are paying them for this, and they still cannot be moved along. So, their comments may not be available to anyone until June or later.

And this sort of throws a wrench in the works. We're not sure how to accommodate that exactly. Our lawyers are looking at it also.

UCLA would love to have their comments as well as the other comments. And somehow it will be worked in and the protocol will address their comments.

What the mechanism is for working this out and particularly surrounding our obligations with UCLA are still up for grabs.

MR. WILSON: Barclay, can I mention something?

DR. SHEPARD: Yes, sure.

MR. WILSON: The State of New Jersey, our State

Commission on Agent Orange has recently sent letters to the Director of Veterans Affairs for all 50 states, Barclay, and, I believe, six territories.

We are having a series of discussions and looking at the possibility of hosting a national conference, possibly in June or shortly after for state commissions that are involved in the Agent Orange question or those states who would contemplate being involved.

And as that list begins to grow, obviously, we're anxious to avoid duplication and to be attuned to efforts that would help to resolve this question rather than to prolong it any longer than necessary.

So, those folks from various states -- make sure your director of veterans' affairs just doesn't send a letter back and say, "we're not anxious to participate," or things of that nature.

DR. SHEPARD: Yes, Dr. Hobson?

DR. HOBSON: The states may very well be asked to assist us in one areas--in what I think is going to be something of a problem in carrying out the epidemiological study.

It is going to take an active participation, at least as subjects of this epidemiological study, on the part of veterans who never were in Vietnam; that is, a Vietnam era control group.

We anticipate some difficulty in getting a

representative, overall, randomly selected sample from that population. And we may come to the states and ask them to solicit for us the cooperation of those Vietnam era veterans in mounting this epidemiological study.

So, we may be coming to you for some help in that regard.

DR. SHEPARD: Yes?

A PARTICIPANT: Yes, a question on the Ranch Hand Study. If I recall correctly a preliminary report on the new follow-up that is to be released this Spring, the Air Force expected their first report on their follow-up questionnaires and follow-up studies.

If so -- my question is, is it going to be released directly or is to be considered and released through one of the other agencies working on Agent Orange?

Is the Air Force going to be releasing to the public directly or through some other agency?

DR. SHEPARD: I'm not clear what report you're referring to when you say there was a report due out this Spring. Can anybody help?

A PARTICIPANT: This August, when the Air Force Ranch Hand Study was reported, they were sending follow-up questionnaires, calling back people who had not been in contact with them for some time.

And as I recall, I thought in the Spring -- they

said, I believe, April, that they expected an initial report on the follow-up.

DR. SHEPARD: Well, let -- as long as you're asking about the Ranch Hand Study, it's my understanding that/they are in the process of interviewing all members of the Ranch Hand group and the controls.

They have started the process of physical examinations. I think some 200 or so, maybe more than that by now, are being examined at the Kelsey-Seybold Clinic in Houston, Texas.

It may be -- the follow-up you refer to applies to those individuals who may initially have expressed some reluctance to begin the thing -- I'm not sure.

Al Young may shed some light on it.

MAJOR YOUNG: It's the contact letters that you refer to.

MR. SUTTON: Right. Yes.

MAJOR YOUNG: Very early, when we started the Air Force/study, we sent out letters to quite a few individuals in trying to locate the Ranch Handers. And then in August we did send out the official contact letter inviting them to participate in the study.

MR. SUTTON: And was it not Spring when this study expected to have some --

MAJOR YOUNG: Well, the Spring report/that is talked about

is/
the mortality report.

MR. SUTTON: Oh, I see.

MAJOR YOUNG: It's the mortality analyses and we have not got a firm date on that yet. But those analyses are almost complete. And the Air Force will probably release them in 1982/

MR. SUTTON: Okay, thank you.

DR. SHEPARD: Are there any other questions?

MR. MULLEN: I'd like to say one thing.

DR. SHEPARD: Sure.

MR. MULLEN: I think one of the biggest hurdles in this whole protocol design business has recently been crossed. I think that hurdle was the development of an adequate exposure index.

And I personally would like to thank Dick Christian over at DoD for providing us with the ladder over that hurdle. I think he's done a tremendous job.

DR. SHEPARD: I'm glad you mentioned that, Fred. I certainly would agree with you that Dick Christian's group and the Department of the Army have been absolutely superb in the handling of this very, very difficult issue, and getting into the record and making some sense out of what's there and what use can be made of them and they've been very, very helpful in advising the Science Panel of the Agent Orange Working Group, and they have made a major contribution in this area. And we certainly endorse your

comments. Thank you.

MR. WILSON: I just wanted to participate in the accolades. I just wanted to -- and I have mentioned this to Dick personally that New Jersey veterans have gone to him in large numbers, and are very, very satisfied with the quick and prompt response and the levels of information that they are providing.

So, good job.

DR. SHEPARD: Dick, we've got some time. Would you like to say something? Maybe you'd like to, if you wish, describe some of the complexities you're dealing with, or whatever else.

MR. CHRISTIAN: I'd like to return those compliments.

DR. SHEPARD: Okay, thank you.

(Laughter.)

MR. LEVOIS: I would like to make one last comment about the epi study and that is, it's not worth doing if it's not accepted by the people that it's supposed to provide information to, primarily, and those are the veterans.

And it might be appropriate for this body to, while you're looking at the protocol, consider these questions of confidentiality and the damage that can be done by biasing a study versus the damage that can be done by the bad will that could be generated by the apparent aura of secrecy, and be ready to comment and give us some guidance

the next time we meet.

I think we need to discuss this fully, because I don't want to jeopardize the study on the basis of good science but bad politics.

DR. SHEPARD: That's a very good point, Maurice. And we certainly would like those comments, not just simply the scientific merit, but some of the political attributes of the conduct and the way that the -- that this whole issue in the protocol has been dealt with, because we need that feedback.

And we particularly look to the members of this panel who represent service organizations to provide us with that, and anybody else as well.

Any members of the panel have anything they'd like to say?

(No response.)

Well, again, we very much appreciate all of your being here, particularly the continued devotion of the members of the Committee and look forward to getting together again in about three months. Thank you.

(Whereupon, at 11:35 a.m., the meeting was adjourned.)

CERTIFICATE

This is to certify that the attached proceedings before the Department: Veterans Administration

In the matter of:

Veterans Administration, Advisory Committee on Health-Related Effects of Herbicides, Thursday, February 25, 1982.

were had as therein appears, and that this is the original transcript thereof for the files of the Department.

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Reporter

I hereby certify that the proceedings and evidence herein are contained fully and accurately, as corrected.

Barclay M. Shepard

BARCLAY M. SHEPARD, M.D.
Chairman, Advisory Committee on Health-Related Effects of Herbicides

May 7, 1982

Veterans Administration

Memorandum

Date: February 25, 1982

To: Agent Orange Policy Coordinating Committee

Subj: Agent Orange Research and Education Office

I. It is the responsibility of the Veterans Administration to help lead the way in resolving the Agent Orange question through our medical and scientific research projects and in the way we respond to Congressional direction, the news media, service organizations, and most importantly individual veterans.

II. We are taking several steps to ensure clear policy guidance and solid management of the many Agent Orange related activities in which the VA is involved:

A. The VA Chief Medical Director, Dr. Donald Custis, and I have worked together on the creation of a new Agent Orange Research and Education Office (AOREO). Recognizing the unusual nature of the Agent Orange issue, the new office will have broad authority in this area which cuts across the entire VA. This new office reports directly to me as the Deputy Administrator and Chairman of the Agent Orange Policy Coordinating Committee (AOPCC). Effective immediately, this will be the lead office for all VA Agent Orange related matters.

DM&S will continue to play a lead role in the VA's Agent Orange program. The Office of Environmental Medicine, headed by Barclay Shepard, M.D., will continue to work with environmental physicians in the field and manage DM&S research in this area with policy guidance and oversight from AOREO. Larry Hobson, M.D., and the Environmental Medicine staff will continue to support Dr. Shepard and the AOREO mission. As the Agent Orange epidemiology study proceeds and other DM&S research projects are considered, the DM&S Research and Development office will be called upon to work closely with the AOREO.

Major Al Young, Ph.D., has over a year remaining on a two-year detail to the VA from the U.S. Air Force.

Major Young is an expert on Phenoxy herbicides and is one of the originators of the Air Force Ranch Hand Agent Orange Epidemiology Study. He will continue to consult on VA Agent Orange research and will work with the Department of Defense (DoD) on all DoD records research matters.

Theodore Woodward, M.D., one of the VA's Distinguished Physicians and Chairman of the Armed Forces Epidemiology Board has joined the Agent Orange team as a consultant.

Maurice LeVois has been appointed director of the new Agent Orange Research and Education Office. Mr. LeVois is a Ph.D. candidate in health psychology and health systems research at the University of California Medical Center in San Francisco. He has a strong health research and management background, with particular expertise in medical information systems and the problems of social and psychological artifact in medical research. This background, along with his training and experience in education makes him especially well qualified for the job.

B. Single Agent Orange Focal Point: It is my intention that Maurice LeVois become the single focal point for all VA Agent Orange matters and that he provide guidance and management oversight in these matters. All VA Agent Orange activities should be coordinated through AOREO.

C. Agent Orange Calendar: In order to keep everyone informed about things that others are doing in this area, I would like to create an Agent Orange calendar:

1. Please report all scheduled Agent Orange meetings, conferences, testimony, etc., to Maurice LeVois as soon as dates and times are set.

2. A calendar of each day's events will be compiled at the close of business the preceeding day. All internal and external Agent Orange activities should be reported.

D. Status Reports: The Office of Environmental Medicine issues a weekly status report on all of their Agent Orange activities. Every other office having any involvement in

Agent Orange related activities should do so as well. This should be a very brief statement concerning the status of each planned and/or ongoing activity. Special events, trips, conferences, etc., should be mentioned. Please submit an Agent Orange activity status report to Maurice LeVois by the close of business on the last working day of each week.

E. Requests for VA Participation in Agent Orange Activities: Special requests for VA participation in Agent Orange related activities sponsored by other agencies and organizations should be reported to Maurice LeVois as soon as they are received. A checklist of information to be obtained from the source of the request will be distributed soon. These requests will be circulated to the appropriate offices for recommendation or action. Routine media requests and requests for specific information should be passed directly to the appropriate offices for immediate response (e.g., Public and Consumer Affairs, and Environmental Medicine). Report all requests to Maurice LeVois.

III. There are several recent Agent Orange developments to report in addition to the creation of a new office:

A. Additional office space has been added to accommodate expansion of our new Agent Orange operation.

B. The U.C.L.A. Agent Orange Epidemiology Protocol has been submitted to the White House Agent Orange Working Group Science Panel and to the Office of Technology Assessment (OTA) for review and comments.

C. The VA is also currently involved in a number of little publicized research efforts including a veterans mortality study, a birth defects study in collaboration with the Centers for Disease Control (CDC), and several clinical laboratory studies. In response to a recent special solicitation for VA research programs involving Agent Orange and Agent Blue, there were affirmative responses for 41 proposals from 31 VA medical centers. These preliminary responses cover a wide range of laboratory, animal and human research topics. They are now undergoing formal research protocol development for an April 15, 1982 submission deadline.

D. The Office of Public and Consumer Affairs has developed the first two in a series of Agent Orange Fact Sheets. The first is a general update and VA Agent Orange status report. The second provides information about Public Law 97-72 of interest to Vietnam veterans. These and future informational materials will be part of a planned direct mail campaign to reach concerned veterans.

E. Plans are underway for increasing Agent Orange Research and Education personnel.

IV. The widespread support at VACO of our reorganization effort has been gratifying. I want to thank all of you who are involved in the VA Agent Orange program.

CHUCK HAGEL

CHARLES T. HAGEL
Deputy Administrator

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

**(Twelfth Meeting
May 13, 1982)**

September 1982

Washington DC 20420

TRANSCRIPT OF PROCEEDINGS

VETERANS ADMINISTRATION

ADVISORY COMMITTEE OF HEALTH-RELATED

EFFECTS OF HERBICIDES

Veterans Administration Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C. 20420

May 13, 1982

The Committee met, pursuant to notice, at 8:30 o'clock, a.m., BARCLAY M. SHEPARD, M.D., Chairman presiding.

MEMBERS PRESENT:

BARCLAY M. SHEPARD, M.D., CHAIRMAN
Special Assistant to the Chief Medical Director (102)
Veterans Administration Central Office
Washington, D.C. 20420

J. DAVID ERICKSON, D.D.S, PH.D.
Birth Defects Branch
Chronic Diseases Division
Center for Environmental Health
Centers for Disease Control
Atlanta, GA 30333

COLONEL RICHARD A. HODDER, M.D,, M.P.H.
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Department of Preventive Medicine
and Biometrics
Uniformed Services University of the Health Sciences
(USUHS)
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National Cancer Institute
National Toxicology Program
National Institutes of Health
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FREDRICK MULLEN, SR.
Claim Consultant, Paralyzed
Veterans of America (817A)
Room 117
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Washington, D.C. 20420

SHELDON D. MURPHY, PH.D.
Department of Pharmacology
University of Texas Medical School
P.O. Box 20708
Houston, TX 77025

ALTERNATES PRESENT:

(For IRVING B. BRICK, M.D.)
THOMAS J. FITZGERALD, M.D.
Medical Consultant
National Veterans Affairs
and Rehabilitation Commission
The American Legion
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Washington, D.C. 20006

(For ADRIAN GROSS, PH.D.)
HENRY SPENCER, PH.D.
Pharmacologist, Toxicology Branch
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U.S. Environmental Protection Agency
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Washington, D.C. 20460

(For ROBERT H. LENHAM)
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Administrative Assistant
National Service and Legislative Headquarters
Disabled American Veterans
807 Maine Avenue, S.W.
Washington, D.C. 20024

I N D E X

DR. SHEPARD: Welcome to another meeting of the VA's Advisory Committee on the Health-Related Effects of Herbicides. We're happy to have you all here this morning and again wish to express the VA's appreciation to the members of the Advisory Committee for their attendance and on-going commitment to this continuingly puzzled issue.

I would remind members of the audience that we have a sign-up registry book in the lobby and we'd like very much for all of you to sign your names there. We have cards and pencils, I understand, for you to prepare your questions. If you haven't picked those up on your way in, Don Rosenblum, the able Executive Secretary of this Committee, will be happy to provide them to you if you'll just indicate to him that you need those materials.

We have a very full agenda as usual this morning, so I think we'd better get started. The members of the Committee have been provided copies of the agenda.

There will be a discussion on the matter of the VA's epidemiological study and how we as a Committee propose to handle the review of that.

An important agenda item, therefore, will be the discussion about holding a closed meeting this afternoon for the purpose of discussing the latest submission of UCLA, that is the protocol for the conduct of our epidemiological study.

Dr. Adrian Gross just called and had an unavoidable conflict, but we're happy to have Dr. Henry Spencer here as his alternate.

Many of you who have been following this issue, and especially the VA's activities regarding the Agent Orange issue, I'm sure you are aware that there has been a change, modest change I would say, but an important change in the organizational structure of the VA dealing with this issue.

To address that and other related matters I'd like to now call on Mr. Maurice LeVois who is the Director of the Agent Orange Education and Resource Office. Maurice.

AGENT ORANGE RESEARCH AND EDUCATION OFFICE

MR. LeVOIS: I'll start out with some general comments just to give those of you who haven't been following these meetings regularly a little background.

The Agent Orange activities within the VA have been addressed primarily by the Department of Medicine and Surgery. Dr. Shepard is the head of the Environmental Medicine office within DM&S that has been and continues to be responsible within DM&S for those activities. With the change of administration, there was an interest in involving more fully all the offices and departments within the Agency, and to do so more formally. This was because the issue is a very broad issue and it involves a number of the other offices as well, as you might imagine, the Department of Veterans Benefits obviously, but also Reports & Statistics, Data

Management & Telecommunications, Public & Consumer Affairs, all of these other offices are also engaged in various types of activities, mostly in support roles.

AOREO serves as a method of coordinating all the other offices and provides the oversight for policy purposes that is now the responsibility of the Deputy Administrator of the VA. So that's who I am and we have passed out, I don't believe that it's in this package, but we passed out at the last meeting an organization chart. That organization chart is probably going to be modified soon.

Again, since our last meeting, we have been engaged in almost continuous budget and program development discussions and part of the effort that's taking place right now organizationally is to get Agent Orange funded, get research funded in a consistent manner, projected out into out years how we intend to support research and support the different activities that we're involved in.

To consolidate the research effort, particularly within DM&S, if you have a copy of the other organization diagram you will note that there is a research box appended to my side of the diagram that reflects the fact that there is research going on in the Agent Orange area outside of DM&S at the moment. We would like to consolidate funding to assure the continuity of funding and to consolidate management of the research in one area.

So, what I'm saying is with our budget package there will probably go a consolidation of some activities and a further reorganization. What was handed out before was a first pass at it and it's apt to be modified further.

Along those lines, it had been suggested to me that as an Advisory Committee to the VA, frequently involved in discussions relating to policy as well as programs and science, that it might be desirable to have a co-chairmanship of this Committee: one member being Dr. Shepard, the representative of DM&S; and one being myself, or whoever would replace me in a change of administration, being a representative of the administrative staff so that communication concerning policy could be formally conducted between both of our offices and the Advisory Committee.

That's a proposal, and I would be happy to have this body, the Advisory Committee, consider it, either today or consider it and make recommendations on it at a future date. However you would like to respond to that suggestion.

That is all I have to say at the moment except that I will have to excuse myself at 10:45 for about thirty to forty-five minutes. We have another meeting involving the demonstration that will be taking place at that time and some of those people have been invited in to have a discussion

with the Deputy Administrator. I'll be attending that for a few minutes and return if I can before we recess for lunch. Dr. Shepard.

DR. SHEPARD: Fine. Thank you very much Maurice. I'd just like again to emphasize that there will be time provided at the close of the meeting for questions from the audience. We would prefer that you write these questions down. We do not insist on that, but we would prefer it. It makes it a little easier to handle, and pass them to Don Rosenblum and so that when the appropriate time arrives in the agenda, we'll be able to address your questions. I think this practice has worked very well in the past, and we would like your cooperation in observing that. So, as questions arise in your minds during the course of the discussion with members of the Committee, please jot them down so that you will have them available to bring to the Committee.

There have been a number of activities going on since our last meeting. Many of them are in the form of on-going efforts that you're already been aware of. I'm sure many of you know that we now are approaching the time when we are going to be starting an epidemiological study, the one mandated by Congress some time ago now. We're very excited about this. As many of you know, there was some

serious questions when this study was first mandated by Congress as to whether this type of study in fact was possible. Many questions at that time were unresolved in matters such as exposure. How can we actually determine with scientific validity who in Vietnam was exposed, and who was not, in order to make some judgments in terms of the effect of that exposure.

All of you know that the Air Force is conducting a study of their Ranch Hand people and their exposure is well-documented. However, for the remainder of the veterans, that has always been a difficult question.

With the very able help of some folks in the Department of Defense and Department of the Army, it now appears that a methodology for establishing an exposure index is in fact in place.

This has been reviewed in great detail by the Science Panel of the Agent Orange Working Group and a recommendation has gone from the Agent Orange Working Group indicating that an exposure index or an exposure likelihood index or the manner of determining which individuals in Vietnam were, in fact, exposed and which were not or had a very low likelihood of exposure. That process has been outlined and the Committee has given its approval to the process therefore indicating that in the scientific opinion of the Committee this is a possible study.

So we are now on the verge of getting that study under way. Very recently correspondence has gone back and forth from the Secretary of Health and Human Services, who chairs the White House Cabinet Counsel on Human Resources to which the Agent Orange Working Group reports.

Correspondence between Secretary Schweiker/ and Secretary of Defense, Mr. Weinberger, and also the Administrator of Veterans Affairs has resulted in specific tasking by the Secretary of Defense for the establishment of a task force to develop the study cohorts.

We view this as a major effort and again commend the Department of Defense and Department of the Army for playing a lead role in this effort. We'll probably have more to say as time goes on, but I just did want to make sure you all understood that and that we in the Veterans Administration are very happy that this decision has been made.

I would like to call on Dr. Hobson now / who will give you a few of the details on the epidemiological study, where we stand. Then / I would like to have some discussion from those members of the Committee who would like to ask questions of Dr. Hobson.

EPIDEMIOLOGICAL STUDY UPDATE

DR. HOBSON: As I am sure you all know, the first submission from UCLA was not deemed to be satisfactory and, after review by three groups, it was sent back for revision

and for the submission of a satisfactory protocol. That protocol in turn when it was received was sent out for review by three groups including this one. The comments resulting from that review were sent back to UCLA and they have now returned their rejoinder to those comments.

Basically I think there are still a number of issues, or were at the time the reviews were taking place, that needed resolution. One of them was the question of the possibility of determining exposure or the likelihood of exposure, and Dr. Shepard has just discussed that with you.

A second one had to do with the inclusion of a third cohort, a group of veterans of the Vietnam era who had never themselves been in Vietnam nor exposed, not only to Agent Orange, but not exposed to the conditions in Vietnam.

The UCLA group on epidemiologic grounds would prefer not to include a third cohort. Other groups have spoken very strongly in favor of including this third cohort as a second control group, one which might enable us to say whether there were effects of Vietnam service apart from exposure to Agent Orange.

A third issue that has arisen is whether the examinations will be conducted by the VA itself or, under contract, by outside groups. This question is still unresolved at the present time and UCLA did not give any strong recommendation

one way or the other on that.

Another issue that came up was the questionnaires.

Many of the comments were directed to the length and content of the questionnaires and to the proposed examination. The questionnaires have been revised, and the examination forms have been changed by UCLA in their current submission. That current submission is being sent out now for review and will be discussed this afternoon in closed session here.

This closed session raises the next issue which has been a rather hot one and has to do with the necessity for retaining details of the protocol in a confidential fashion. UCLA feels very strongly that the content of particularly the questionnaires and the examination should not be revealed for epidemiological reasons.

Epidemiologists are divided on this subject. Some feel that it is necessary to keep them confidential; some feel that it is not necessary. Under these circumstances, it will be necessary for the VA, I think, to be prudent if we're going to maintain the scientific accuracy of the study, but the decision has not been made as to how generally we will distribute the questionnaire prior to its use.

Whether we distribute it before the study does not influence what we will do after the study in my opinion. The questionnaire with all details will certainly be made public

as soon as the study is completed and there is no likelihood that disclosure would in any way influence or bias the results. So we're not talking about keeping something secret in perpetuity. We're talking about meeting a scientific necessity if we decide not to disclose the contents of the questionnaires.

DR. SHEPARD: Thank you Dr. Hobson.

MR. LeVOIS: DR. Shepard, could I make one --

DR. SHEPARD: Yes, certainly.

MR. LeVOIS: One comment, something I would like to add so that when we get to the point where we have an open discussion we're prepared to discuss it. UCLA recommended against a third cohort on the basis of non-comparability. They suggest that those troops who did not go to Vietnam differ in at least a couple of ways from those troops who went to Vietnam and came back.

In the first place, they may have been self selected out of going to Vietnam. They may have chosen desk jobs, or different types of jobs that make them different. They may have been socio-economically different, and there may be ways in which those who were selected for service in Vietnam differ from those who weren't.

And there may also be differences between those who didn't go to Vietnam and those who went and survived because those that went and came back and would enter the study are

survivors. So they're pointing out there may be, and of course, they don't cite any evidence of this, but they think logically there may be differences between those people who would choose who were veterans but never went to Vietnam and those veterans who went to Vietnam and came back. That's something we need to consider, the comparability of that third cohort. There are ways to address that which I think we'll get into later.

DR. SHEPARD: Are there any questions, comments, from members of the Committee on these issues? Yes, Dr. Erickson?

DR. ERICKSON: Can you tell us what the plans are once this third review is completed? You said we're about ready to get under way. What does that mean?

DR. SHEPARD: Okay, one of the evident things, it seems to me, is that we will have to consider how we'll go about the data collection system. One of those elements, as you well know, is a questionnaire and it seems appropriate that the VA contract out the development of a questionnaire, the pre-testing or pilot testing of the questionnaire, and then the administration of the questionnaire. Whether that should all be done under one contract, or whether it should be done under a phased contract with one contractor, or whether it should be separate contractors are technical questions that we'll be addressing, but that is one way in

which we'll be involved very soon I believe.

A major question still unresolved is who will actually conduct the physical examinations, so that we'll be doing some testing of that. One of those will probably involve a cost benefit analysis to determine what the relative cost would be of conducting the physical examinations in-house versus by contract.

We would also encourage comments from groups representing veterans to get their feel for their attitudes on this point. Clearly, participation in a study of this magnitude is extremely important, and I think it behooves the Veterans Administration to assure maximum participation. To that end we need input from veterans groups as well as members of Congress, scientists, anybody who has an interest in this area, to provide us with issues which would help guide us in making that decision.

DR. ERICKSON: Thank you.

DR. HOBSON: We are away from the update now, we're in the future date, but it will be necessary to refine instruments particularly through field trials of those specific instruments. Even after that is done there will have to be a pre-trial run with a comparatively small number of veterans-- we're now thinking of around nine hundred to smooth out the techniques that will be used in the conduct of the major portion of the trial.

This trial is one of the most extensive that has ever been attempted in the detail we're considering, and unquestionably there are going be gliches that appear in the early stages. We would like to rule out as many of those as we can and get them straightened away during a pre-trial with a small number.

Then we would go to the full trial, whether it's to be done within the VA or outside.

DR. SHEPARD: Dr. FitzGerald.

DR. FITZGERALD: Has there been any more consideration on the question of independent supervision of the study, that is independent of the VA?

DR. SHEPARD: Yes sir. We are pretty much agreed that as was the case in the Ranch Hand study that there should be a non-VA oversight committee to provide a number of elements, scientific expertise, assurance of compliance with the protocol when we finally have an agreed upon protocol, and in addition, we are concerned about protecting the rights of the study's subjects, and so we feel that there should be a human rights committee. Whether that is a separate committee or part of the same committee, I think is a question still unresolved, but my personal feeling is, and I'm speaking simply as an individual, that it probably would be best to have those as separate bodies.

Yes?

MR. LeVOIS: I would just like to underscore something that was already said which is the decision as to who will do the study, whether it will be done by the VA in part or in whole, or not at all, has not yet been made. We are committed to oversight just as Ranch Hand has an oversight body in addition to the science panel and OTA, a panel of experts set up with the sole function of the oversight of Ranch Hand. We would have the same kind of body undoubtedly set up. We'll discuss that later or we could discuss it more fully now. The composition of such a body certainly is something that our Advisory Committee would be asked for input on. The mix between experts and veterans possibly would be very important. I hope that it's clear that we haven't decided that this is a VA in-house study, that that decision has not been made, and will be influenced on a number of factors as has already been mentioned, including thorough evaluation of the pilot test and participation rates, the effects of doing it in-house and out-house, the cost of doing it in-house and out-house, the feelings of Congress and the veterans service organizations, and this Committee of course.

DR. SHEPARD: Dr. Hobson.

DR. HOBSON: In a study of this magnitude, one of the principal problems that one has, of course, is quality control, and I have a feeling that a good part of our effort

is going to be going into quality control of the running of trial. That certainly will be under the supervision of an outside body. It will require repeated scientific audits of the work, I'm sure. I don't mean financial audits, but the science, how the data are collected and how they're reported and handled afterwards. And we expect all of that to be done under the supervision of an advisory group on the outside.

DR. SHEPARD: Dr. Erickson.

DR. ERICKSON: As Dr. Hobson just pointed out, you're starting out an enormous study. It's an epidemiological study and I wonder if you have given any consideration to getting an epidemiologist or a small team of epidemiologists to join your team in-house? It would seem to me that would be a wise thing to do.

DR. SHEPARD: Yes. One of the proposals that is in our funding request package, if you will, is precisely that, to establish within the VA a projects office, a special projects office for the overall management and supervision of this study regardless of who actually does the study. So we are looking very definitely to bringing on at least one epidemiologist with proven expertise in this area.

If any members of the Committee have recommendations for either recruiting or actually identifying any such individual, we would certainly welcome that, but I'm glad you mentioned that

Dr. Erickson because that's obviously a very important element.

Any other questions?

DR. ERICKSON: Is there a group within VA from which you can recruit?

DR. SHEPARD: Not really. There are a few epidemiologists in the VA. They are employed in the field. There is no group of epidemiologists per se, so constituted within central office. In other words, there's not a department or division of epidemiological research. We feel that it would be important to establish such a group, and we are making moves in that direction.

MR. LeVOIS: I can add that one of the first efforts that I undertook was to try to evaluate what our capability was of doing large scale population based epidemiology. There are a number of people in the VA who are epidemiologists. It turns out that they're hospital based epidemiologists looking at the control of infectious disease within food service and operating rooms etc. That sort of thing. Not the kinds of qualifications we're looking for to oversee this type of study, so unfortunately, we don't have a ready pool of people. We have budgeted for that office and for that so that we can bring those people in. That's why we don't have someone on board already.

DR. SHEPARD: Yes, Dr. Murphy.

DR. MURPHY: What, are you looking for is the possibility of two potential additional negotiations for contract. Presumably the pilot study as well as the full study will be conducted in-house, but also the possibility is, as I understand it, that one or more institutions will be contracted to do this.

DR. SHEPARD: Excuse me, I may have misled you. What I tried to indicate was that I think that no matter what is done in terms of the total study being done in-house or out-house, I think that since we don't have the expertise within the VA to develop and pretest a questionnaire, it will be done under contract.

The VA has done many surveys as you well know, but surveys of any magnitude, as far as I know, without exception have been done under contract. I think that it's a given that we would do the majority of questionnaire development, pretesting, administration, and so forth by contract.

DR. MURPHY: Well, I'm merely trying to get some idea of the time frame that we're talking about whenever this firm proposal gets accepted or otherwise. Let's assume that it's accepted, then there has to be another request for proposal, another review of the protocol / or is that going to be so clear cut based upon proposal that UCLA group is doing, that there isn't really any room for negotiating, something needs

to be done, contract request for proposal, request for -- (REST OF QUESTION INAUDIBLE)

DR. SHEPARD: I think, my thinking is, more along the latter, that before very long we will have an approved protocol, or the VA will say okay this is it. There will be some fine tuning of that protocol probably as time goes on. The basic outline, as I hope you will see this afternoon if you're able to stay for the meeting, is pretty much in place. Then the question in the contracts would then be in the request for proposal would go out for those elements which appropriately should be done by contract.

Have I answered your question?

DR. MURPHY: Well, yes I guess so. With the time frame we're talking about, when will full study likely begin?

DR. SHEPARD: Well, if by begin you mean the development of the questionnaire, the final questionaire, elements of the questionnaire are contained the present proposal. There is a questionnaire in the proposal. I am not satisfied myself, and that's largely because we're not experts in this particular area, as expert as one should be. There will have to be some fine tuning of a questionnaire, actually the development of the document itself. It seems to me that we can go out with a request for proposal very soon for that contract.

There's one thing we haven't mentioned. We are now I believe in the final stages of signing a contract with the National Academy of Sciences to also review the protocol. That effort will take approximately two to three months, so I guess it's safe to say that we will not have a final approved protocol until about two or three months from now.

In that interim, however, certain elements can move forward, so I don't think we have to wait for the NAS review to be completed before we can issue a request for proposal for the questionnaire development.

DR. MURPHY: The NAS review of this proposal, it's current revision --

DR. SHEPARD: That's correct, yes, the final submission which just came in a short time ago.

DR. MOSES: Is that going to be the same NAS committee that reviewed the Agent Orange, I mean the Ranch Hand?

DR. SHEPARD: No ma'am.

DR. MOSES: I just asked if it would be the same NAS Committee that reviewed the Ranch Hand.

DR. HOBSON: I can amplify that a little bit. The Ranch Hand proposal was submitted to the toxicology group at NAS. We felt that ours was an epidemiological study and we should ask that it be reviewed by the Medical Follow-up

Agency and its epidemiological advisory committee rather than a toxicology committee.

Incidentally, there can be a tremendous amount of overlap. There's nothing that says we cannot go out with an RFP for the fine tuning and field testing of a questionnaire at the same time the NAS is conducting its deliberations.

DR. MOSES: Could I just ask one more question?

DR. HOBSON: Sure.

DR. MOSES: I was really impressed with the -- attempt to handle the exposure in this thing, and all the time, energy and effort they put into this. I hope there will be some plan to keep these people in some sort of capacity involving study where it's at (REST OF QUESTION INAUDIBLE)

DR. SHEPARD: The contract as such expires with the submission of this protocol, or this design, this proposal. There's no commitment one way or the other to continue any relationship with UCLA. That also does not preclude any possibility that there may be ongoing relationships, so I think that question is still open, but there are no specific plans currently in place to continue the relationship on any contractual basis.

MR. LeVOIS: Concerning the exposure index, Dr. Spivey actually I believe had less to do with that part of the protocol than any other. That was borrowed almost intact

from the Department of the, well no, from the Army Agent Orange task force and DOD development efforts, so --

DR. MOSES: Congratulations.

MR. LeVOIS: -- so, in that respect we'll have continuing input from the people who have, at least it looks like they've, gone a long ways toward ironing out the most difficult part of the study.

DR. SHEPARD: Any other questions on the proposed study from members of the Committee? Comments? Okay, thank you very much.

VA MORTALITY STUDY

As many of you know, the VA, for some time, has been looking at the possibility of developing a mortality study largely based on the fact that the VA has an unusual resource at its fingertips, in that the BIRLS file contains the names of a very high percentage of veterans who have died based on burial benefits claims. This is a resource that has been suggested to utilized in the development of a mortality study. We have been proceeding along the lines of exploring that whole effort are now at the stage of having something that we think has a strong potential for being a very important research effort. To bring you up to date on where we stand, I'd like to call on Dr. William Page from our Biometrics Division. Bill.

DR. PAGE: Thank you Barclay. As I reported last time, there have been some major changes in the scope of the

mortality study. I think I'll give you more detail on that today, that's what I'll talk about basically. Let me begin first by reiterating for those of you who are not familiar with the mortality study that a few ground rules should be laid down. With respect to this, first of all, we should say it is a mortality study so we're only studying one aspect of health, that particular health outcome being death and death rates among Vietnam era veterans.

Secondly, it is not an Agent Orange study per se. I think it may have a lot to say about the general health of Vietnam veterans, but it won't talk about Agent Orange exposure. It will be comparing death rates among veterans who served in Vietnam and veterans who did not serve in Vietnam.

With that as background let me move on to some discussion about the overview of the study. The Vietnam veteran mortality study is fundamentally two distinct studies with some common elements.

The first study is a non-population based proportional mortality ratio study, the so called PMR study, and that's a study of non-military service deaths among Vietnam era veterans of the Army or Marines for the period 1965 to 1981. That's one of the major portions of the study, a non-population based study.

The second study is different in that it is a population

based study. It's a standardized mortality ratio study, the so called SMR, and that's the terminology I'll use, and that's a study of a large cohort of veterans. The second study is a cohort study. It deals likewise with non-military service deaths among Army and Marine personnel, but it covers a shorter period, only fiscal years '73 through '80. Now the shorthand reference to these two studies, as I said before will be the PMR study, the non-population based, and the SMR study, the population based cohort study.

The common element of these two studies is the data-bases that they draw on. As I already mentioned, the BIRLS study is a major common element for both of them.

Let me say a few more words now about the distinction between those two types of studies. The key distinction between a PMR and an SMR study is a distinction between a population based and non-population based study. In the PMR study we will compare the number of deaths for a specific cause with a total number of death from all causes. That will give us what one might eventually call a cause of death profile.

This comparison of the two numbers of deaths does not require us to know the at-risk population, so we will not be able to compute true rates. Now if there is any fundamental shortcoming of a PMR study, that's the fundamental

shortcoming. We won't be able to compute true death rates. We will be able to compute only relative mortality from specific kinds of causes of death.

Now it turns out fortuitously that the strength of the SMR study is where the weakness of the PMR study is; namely, the SMR study is population based and we will know the at-risk population. We'll have a roster of military service personnel, and we will check this roster to count those who have died and hence we will be able to compute true death rates by dividing number of deaths by population.

We will also be able to standardize death rates. In both cases we have the age, race and sex of the veterans that we're dealing with. The only drawback, and I guess the major drawback of the SMR study, which is population based, is that we don't have the total Vietnam era population. In particular, we have only about half of the nine million veterans on our veteran roster for the SMR study. Nevertheless, this is a sizable cohort and it will provide us with, as I say the complimentary data to the PMR study.

DR. MOSES: What percentage do you have?

DR. PAGE: Four and a half million, about one-half of the whole cohort. So I would say, summing up, that the two studies together are really stronger than the separate pieces. Each study in some way compensates for the limitations of

the other. I talked before about the BIRLS file so I won't mention anything more about that today. I should say that one of the sources of Vietnam service for the SMR study, and I've talked about that before, is the so-called DMDC file.

That's a DOD personnel file. For the non-population based study those files are not available and we will have to actually go back to military service records. That's one of the new wrinkles on the study.

With that overview just let me close by saying that the Vietnam veteran mortality study will provide a large scale analysis of deaths among the Vietnam era veterans. We expect to get high quality information on the causes of death comparing Vietnam service and non-Vietnam service veterans.

The fundamental push of the study is to generate some hypotheses that can lead us to design more definitive studies; for example, case control studies and limited number of cause of death studies, or perhaps studies using more defined risk variables. The mortality study is a study to generate some hypotheses. It's not an Agent Orange per se, but I think it will have some very valuable information on the whole picture of health among the Vietnam era veterans.

Any questions from the panel?

DR. MOSES: Will this continue? I mean will you continue to follow deaths from now until about twenty or

thirty years or however long it takes?

DR. PAGE: We should have the mechanisms for us to do that kind of thing. Now that may get a little bit tricky. We may have to switch from the BIRLS file to the National Death Index. There may be some difficulties in the reporting of deaths to BIRLS. In fact, there have been some legislative changes already. We don't know how that will affect the BIRLS files, but we should be able to use, at least in some cases, the National Death Index as a source.

DR. MOSES: Since they are still relatively young men / it seems that is going to take a few years. going to be

DR. PAGE: Oh, that is true. Even from '65 we're only talking about a twenty year follow up.

DR. MOSES: Right.

DR. PAGE: But, we have to take a first shot and this seems like a good time to do one.

DR. MOSES: No, it's very good. I'm just suggesting it should be continued.

DR. PAGE: I agree.

DR. SHEPARD: As a matter of fact, Dr. Moses, the science panel has been working very closely with Dr. Page and his group in the development of this protocol. It made some very helpful suggestions, not the least of which is that it seems important that the Veterans Administration maintain prospectively a cause of death registry, certainly

for the Vietnam era veterans and we hope to get funding for a feasibility study to look at that, the mechanics of doing that. I think that's a very important thing since we do have this valuable resource at our fingertips, as far as I know no other organization in the world has a way of tracking large numbers of individuals who die and therefore have a ready access to a cause of death.

States report causes of death and so forth, but that does not isolate any particular group of individuals. I think we have a special resource here that we all feel is very important to build on.

Yes, Dr. Lingeman?

DR. LINGEMAN: What is your population base?

DR. PAGE: The population base for the SMR cohort is four and a half million automated records that we can get our hands on. It is the DOD/personnel files. Basically, that's the basic source.

DR. MOSES: Is there any way that you can get up to find the other people, to broaden that base?

DR. PAGE: Not easily, no.

DR. MOSES: It's only fifty percent of the total population.

DR. PAGE: Well, the fifty percent -- level are quite useful. That's why the science panel urges we do the PRM study on the whole population.

DR. MOSES: Yes.

DR. PAGE: So I think we're stuck with that, that basic fault if you will in both of those kinds of studies.

MR. LeVOIS: I presume one of the flaws would be that these people would be to some degree self selected. In other words they wouldn't, they would have been called to the attention of the Veterans Administration in some manner?

DR. PAGE: (SHAKES HEAD NEGATIVELY) It turns out these are people on a roster who served between fiscal years '71, '72 or '73. People could have been serving as early as during World War II and still be serving in '71, so that file goes back quite a ways. We don't have just three years worth of people, we have four and a half million people on that roster. That's just the way the automated files turned out. I think it was kind of a lucky break. Very few people have run into these kinds of things at all.

DR. SHEPARD: Maybe it isn't clear to everybody. The BIRLS is an automated system which among many other things has a very high percentage of veterans who have died based on the fact that VA provides a burial benefit. In

order to get that burial benefit one has to file a claim with the Veterans Administration. That causes that individual's name and social security number, to be placed on BIRLS. A death certificate has to be submitted by the claimant in order to get the burial benefit. The location of that death certificate is indicated on the BIRLS file. The National Academy of Sciences did a study and I think they came up with I think ninety-five, ninety-seven percent completeness of the death reporting to the non-automated predecessor of the currently automated file. That completeness by the way will be assessed for the BIRLS file. BIRLS then provides the VA with a very complete list of all veterans who have died and where their death certificates are filed, and therefore gives us the opportunity to search those death certificates for causes of death.

MR. LEVOIS: The other part of it, the four million are the DMDC records, the automated records of DMDC. That's where the selection down to a fifty percent sample comes in. We bounce some very complete death records against the military records which are only half complete, but our understanding is that there is no systematic reason why these people are in there except for

their time of discharge, and that it covers people who may have been in the service for ten years, five years, two years. It covers almost the entire Vietnam era and it appears to be a fairly representative fifty percent.

We have an intention to look at its completeness and representativeness also, but if it does turn out to be not systematically biased in any way, it should be a very good thing to bounce the BIRLS off of it, and it should give good quality information.

DR. MOSES: Is there going to be any attempt to validate any of the, knowing what we all know about the probable death certificate, the diagnosis, is there going to be any -- -- to validate it? I'm just asking if there is going to be any attempt to validate the cause of death stated on the death certificate in at least a certain percentage of them?

DR. PAGE: We're going to have a lot of validation studies going. We have to validate the DMDC personnel / service record against the military personnel records, the actual paper records, and we have to validate the BIRLS file and how complete it is. We have / plans right now to go back to the death records. We will be making a comparison of death certificates from both groups so on the average those kinds of biases should even out. I think if we find some causes that begin to stick out, that's when we will probably go back, retroactively.

DR. ERICKSON: Do you have any rough idea of how many deaths you expect to find at this point in time, doing some rough calculations?

DR. PAGE: Yes, we've done some rough calculations. We expect in the whole population actually more deaths than we need to include in the study. We'll probably be sampling in the range of fifty to seventy-five thousand of these deaths for the PMR study.

DR. ERICKSON: Fifty to seventy-five thousand. Well, you know the Department of Defense, Department of the Army developed some (it seems reasonable) methods to determine Agent Orange exposure--not in a definitive way like would be used for the main epidemiological study, but nevertheless a satisfactory way. It would be quite easy for you to turn this into something of an Agent Orange study by using a case control approach. You take deaths as cases and a sample of non-deaths and try to assess Agent Orange exposure in the cases and controls. You might add something, a substance to the study without a whole lot of effort. A point for your consideration.

DR. PAGE: That's a little surprise we've been saving for DOD, but you're just suggesting that if we do find something in the PMR or SMR study that shows a disproportionate number then we could focus in on only those cases as cases and then go back to the military and not force them

to go through seventy thousand records.

DR. ERICKSON: That would be too many.

DR. PAGE: Yes.

DR. ERICKSON: That's why I asked how many deaths you expected to find. Seventy thousand is obviously too many. You either might split it out on the basis of as you suggest on some cause of death that sticks out, or you might even just do a sample of it, a sample of the seventy thousand, a sample of non-deaths as controls.

DR. SHEPARD: Any other comments? Yes, Dr. Lingeman.

DR. LINGEMAN: You certainly should be able to identify changes that are of interest in specific target tissues, such as defects in the immune system. We have some ideas about what kinds of things to look for. Would it be epidemiologically possible or correct to emphasize the target organs that we know are likely to be affected by TCDD?

DR. PAGE: We will be doing cause of death profiles So that soft tissue sarcoma is a special cause of death we'll be looking at. There's no doubt about that.

DR. ERICKSON: For example, a lot of those deaths are probably accidental or from other things of that sort which would generally rule out as being causally related --

PROPOSED TWIN STUDY

DR. SHEPARD: Okay. Thank you very much. Next we'd like to call on Dr. Alvin Young on loan to the VA from the U. S. Air Force

to describe what is emerging as a very interesting proposal.

DR. YOUNG: One of the problems that we've talked about with respect to the epidemiologic study, the ground troop study, is the time it is going to take to conduct such a study. There's an awful lot of us that are very concerned about the number of years that are going to be required and so in an effort to look at perhaps something that would take less time to conduct, the twin study has come to our attention.

In addition, various studies are being proposed. (e.g., VA epidemiologic study and the Air Force health study)

that focus on health outcomes that are "rather easy to recognize", for example cancer, perhaps birth defects.

But one of the things you hear a lot about from veterans are symptoms that are very different than that. As a matter of fact, there are symptoms that have been reported following the TCDD involved industrial accidents. For example, we talked about persistent headaches, apathy, fatigue, muscle pain, joint pain, anorexia, that is loss of appetite, weight loss, sleep disturbances, decreased learning abilities, decreased memory, sexual disfunction.

These are things that are very difficult in a large scale epidemiological study to examine. For example, if our study involves eighteen thousand ground troops it's going to be very difficult to focus in on those kind of subtle differ-

ences because part of what you need is an individual who is very close to you that can serve as a control, that has had basically many of the same experiences in life but perhaps the different experiences would be Vietnam and say non-Vietnam or Agent Orange exposure and non-Agent Orange exposure.

Well, the St. Louis VA Medical Center has a group of personnel that have suggested to us the possibility of conducting what we would call an identical twin study. Now identical twins have a physiologic characteristic, in that they're identical in terms of certain blood parameters, body characteristics. They have a history of being identical. Most of them are raised under the same environments and what would look for would be about four hundred twins where one member of the twin pair served in Vietnam, the other twin pair, the other member of the pair, would have served in the military, but not in Vietnam.

Now, what is the likelihood of finding say four hundred pairs? Well, if you look at the population figures and you make some calculations, what you find is about seventy-two hundred twin pairs like that were represented in the Vietnam experience. So we would need to establish a registry, try to locate, through various State efforts perhaps, four hundred pairs of twins, and as a matter of fact, there is a recommendation on the establishment of such a twin registry.

Now, once you have those four hundred twin pairs you'd

want to bring them to a same central facility and then using very very sensitive physiologic, psychologic and biochemical examinations, you should be able to detect perhaps differences that would exist as a consequence of the difference in experiences these individuals have had.

Identical twins not only have a common background, but there are characteristics, for example blood characteristics, that should be identical. They should be "in concordance". The concordant characteristics, we would expect them to have the same sort of blood pressure, and there should be a degree of concordance in that blood pressure.

Well we would take all of these various carefully obtained parameters and look for this characteristic called concordance, and we would see if we could relate that concordance and the differences for example in Vietnam experience.

Simultaneously we would attempt to try to find what sort of an exposure index these individuals would have had to Agent Orange. Now we're only talking about the four hundred that would have served in Vietnam of course in that regard.

It's a very interesting proposal. The St. Louis group have put a recommendation in to develop a proposal. This Advisory Committee certainly ought to think about the value

of such a twin study. If a proposal is in fact received to develop a protocol, the protocol would have to undergo, a very extensive review and I expect that this body would serve as part of that review.

It's a very interesting idea, one that we think is very exciting. At this stage, of course, it's only a proposal and we're hoping to see how this particular proposal develops.

DR. SHEPARD: Thank you very much, Dr. Young. Any questions?

DR. ERICKSON: Could you briefly tell us how you figured out your seventy-two hundred. Is that out of the roughly eight million?

DR. YOUNG: Out of the 10 million that served in Vietnam you can calculate that about ninety thousand pairs of twins would have been involved. You make some other calculations on percentage that both would have gone, percentages that one would have gone, you come down to about seventy-two hundred pairs. Now that can't be an exact figure because we don't know what it would have been.

DR. ERICKSON: But it's based on the two and a half million.

DR. YOUNG: On ten million and the likelihood of twinning.

MR. LeVOIS: Which I think is .2 percent, something

like that, of the population.

DR. ERICKSON: For identical twins.

MR. LeVOIS: For identical twinning, yes.

DR. YOUNG: We're talking about -- twins, identical twins.

DR. MOSES: Do you know how many -- twins because that would be, you know --

DR. YOUNG: We've talked about that, and there would be a lot more -- but we specifically want to be focused on the case of identical / twins.

DR. MOSES: I find that very interesting.

DR. YOUNG: A very interesting concept, a very exciting concept. The whole area of twin research is really catching on now. Twin study on the Vietnam issue / could be very interesting, very exciting.

DR. SHEPARD: Any other questions, comments from the members of the Committee?

DR. LINGEMAN: I guess you touched briefly in establishing concordance is the big issue here because of, well if somebody says they're identical, they may or may not be.

DR. YOUNG: We have concordance on such things as the MMPI. We have concordance on whole series of blood parameters, blood sugars.

DR. SHEPARD: You're speaking about establishing

monozyotic twins?

DR. LINGEMAN: Right, right.

DR. SHEPARD: There are some rather sensitive tests to distinguish between identical twins and fraternal twins. Any other comments? You don't agree Dr. Erickson?

DR. ERICKSON: I don't know, my calculations would suggest about half that many. Did you wipe out female pairs?

DR. YOUNG: AS a matter of fact we did. Well, I think the issue will be, it's going to take at least four hundred pairs to get the statistical power we need, and if you cannot find four hundred pairs, that would eliminate the situation right there.

Interestingly enough the State of Wisconsin has a registry already and their registry right now contains eighty nine twin pairs where one served in Vietnam and one did not, and that other individual who did not serve in Vietnam did serve in the military. So the registry already consists of eighty nine for only one state, the State of Wisconsin. So we think it can be done. It just needs to have the concurrence, the support.

VA SOLICITED IN-HOUSE RESEARCH

DR. SHEPARD: Okay. Thank you very much Al. Next I'd like to call on Dr. Matthew Kinnard to bring us up to date on the solicitation for in-house VA research relating to Agent Orange and Agent Blue.

DR. KINNARD: Thank you Barclay. Good morning.

In response to Research and Development's solicitation of research proposals to study the impact of the exposure of Agent Orange and Agent Blue on biological models, we've received thirty six proposals. These proposals were submitted from twenty seven separate medical centers. The difference in numbers is accounted for by the fact that some individuals submitted more than one proposal, and in some instances, two or three investigators submitted proposals from the same medical center.

These proposals encompass scientific discipline such as pathology, cytogenetics, behavior and neurobiology and toxicology. Among these four major disciplines, there are several sub-disciplines represented. Included in the thirty six proposals, thirty-one were Agent Orange related, while only five were Agent Blue or cacodylic acid related.

We're starting to identify persons to serve on a review committee which is tentatively scheduled to meet the latter part of June. Approved projects could be funded as early as July 1982 if the funds are made available.

Currently, as most of you know, Research and Development has no funds for the remainder of FY 82 to support any projects whether it be Agent Orange or other merit reviewed studies that we customarily review and fund.

There were twelve principal investigators who answered the call in January to submit titles of proposed research projects. Now each on of those persons have been contacted and advised that they may submit proposals in any subsequent round of our

regular merit review. The next merit review round is scheduled for October of this year. Most of the individuals contacted expressed a desire to continue to work on their proposals which they were not able to prepare in time to submit for the special solicitation. Most of them stated that they will be submitting a proposal for a subsequent round of regular merit review. Thank you.

DR. SHEPARD: Thank you Matt. Are there any questions for Dr. Kinnard from the Committee? Yes, Dr. Murphy.

DR. MURPHY: Well, are these medical centers all VA? This is in-house, is that correct?

DR. KINNARD: Oh yes.

DR. MURPHY: What are the twelve you said, these twelve in addition to thirty six --

DR. KINNARD: Let me amplify that. In January we sent out a TWX to all one hundred and eighty VA medical centers asking them to submit titles and names of principal investigators who contemplated submitting proposals for the April 15 deadline. What I'm saying is that twelve of the people who said in January they wanted to submit, for various reasons, did not submit.

DR. MURPHY: I see.

DR. KINNARD: Therefore, I felt it was necessary to contact them to find out what the rationale for not submitting was.

DR. MURPHY: But thirty-six is --

DR. KINNARD: (NODS HEAD IN THE AFFIRMATIVE)

DR. SHEPARD: Any other questions or comments?

DR. MURPHY: What is the likelihood of getting funds? I mean Barclay said it could start in July but how could you if there's no pot.

DR. KINNARD: Dr. Shepard will / respond to that/ question.

DR. SHEPARD: I have alluded from time to time lately to efforts to solicit funding for some of our Agent Orange related projects and this is one of them. We have requested funding for a group of studies to which Dr. Kinnard has alluded, and we hope to have those funds made available to us sometime during this fiscal year.

MR. LeVOIS: We have a very complete budget package. That budget package will be taken to the Hill very shortly within a matter of a week or two. When that goes to the Hill, that's going to be reviewed within the entire VA budget request for '82-'83.

We have confidence that we'll get the money transferred. We hope that we have reason to be confident. For '82 we can transfer the funds and get started on these projects right away. For '83 there have been all sorts of discussions about cut-backs, and we don't know what they'll do with our request, but we're hopeful. We have a feeling that since Congress has mandated research in this area they have expressed an interest and will put the money into it to see that the work is carried

out.

DR. SHEPARD: Yes, Dr. Lingeman.

DR. LINGEMAN: Was there any attempt on your part to target the research, or was it strictly left up to the people you're submitting the proposals to select the project?

DR. KINNARD: There was a very minor attempt on our part to focus the research. I think, however, that the only thing that was we put in our announcement that was restrictive/that the studies should be confined to animal model systems since it was so difficult to make a determination of exposure of individuals. That's about the only restriction that we required in our announcement.

DR. LINGEMAN: Then I would like to ask Dr. Shepard if there is any other plan or mechanism, maybe on a contract basis, to find answers to some of the other questions that still have not been resolved. There are many questions about the toxicology of these materials, and if we don't get proposals from VA hospitals designed to answer those specific questions, is there any mechanism for awarding contracts for specific studies?

DR. SHEPARD: I think that opportunity always exists. The question again is funding and trying to decide which, what types of projects would be the most helpful. As you know the science panel of the Agent Orange Working Group is constantly coming up with ideas, recommendations, or discussions relating to this type of research, so yes I think

that there is an opportunity and if you have some ideas about research efforts that could be conducted under contract we'd be more than happy to hear about it.

Yes, Dr. Murphy.

DR. MURPHY: I'm just wondering what kind of funding you're talking about with thirty six proposals, if you've determined whether these thirty six are worth funding or not.

DR. KINNARD: No, we have not.

DR. SHEPARD: The merit review process will hopefully make that determination. I think we have targeted something like two hundred and fifty thousand dollars in this fiscal year. Hopefully, if we get all that money, we hope that we'll have enough projects that can be funded and I hope we have the money to match the projects that are worthy of being funded.

But that's the ball park figure we're talking about in this fiscal year, and then of course there'll be some future year funding that will be required if these are approved and funded.

DR. MURPHY: The epidemiological studies are funded, that is the question, is that correct?

DR. SHEPARD: The epidemiological study is budgeted for, but as far as I know the only money, it hasn't even been spent yet, is for the contract for UCLA when that is finally

approved and then UCLA will get a check for that contract.

DR. MURPHY: Well, I really guess what I'm asking is you aren't going out with a proposal here with a question as to whether there will be funds to support it -- that has been budgeted and the funds are there when your decision is made to go for it.

DR. SHEPARD: Hopefully. That decision has not been finally made. We've put in a request for funding for those specially solicited research. We've had good support all the way.

DR. MURPHY: I don't mean that. I mean the epidemiological study, the questionnaire validation study, the ultimate study.

DR. SHEPARD: We have also requested funding for those elements of the epidemiological study that we can get started in this fiscal year and additional funds for the out years.

There have been monies appropriated. Congress has appropriated money for certain elements for the epidemiologic study starting in FY '82. So there is money in the VA's budget for the conduct of the study.

DR. KINNARD: Dr. Lingeman, you earlier asked Dr. Shepard a question concerning whether there would be opportunities for contract research in the area. I just want to back up a minute for that question and say that we did not specifically

of research scientific
dictate the direction /or the/ disciplines that the investigator
they
should come in for because we felt that / should have the
since our knowledge base is so thin.
freedom to select any area they wanted to / To empha-
size what has been previously said, seventeen of the
thirty-six proposals we have awaiting review are in the
area of some aspect of toxicology.

The others break out into cytogenetics, pathology and
by far as you can see
neurobiology and behavior. The largest group /
is in
toxicology.

CDC BIRTH DEFECTS STUDY

DR. SHEPARD: Okay, thank you very much Matt. I'd like to deviate from the agenda a little bit and ask now if Dr. Erickson would like to bring us up to date on the status of the CDC birth defects study. Dr. Erickson.

DR. ERICKSON: Just a review, our study is a case-control study based on a registry of babies born with birth defects in the metro Atlanta area, which is where the Center for Disease Control is, assembled over the past fourteen years. The cases will be roughly seventy-five hundred families of babies who were born with major defects in that time period, and thecontrols, which will number about three thousand, will be chosen from the State of Georgia Vital Records.

We have recently completed a pilot study and I want to share with you now the results, some of the results of that pilot study. I want to emphasize though that I am not going

present any study results in the usual sense of the word. We have made no analysis of these data for birth defect risk factors. We haven't done it now and we don't plan to do it in the future. Specifically, we haven't looked to see whether there were more fathers who served in Vietnam among the cases or the controls. We don't plan to make any analysis of that sort until we have completed data collection from the main study.

The purpose of the pilot study was to test our procedures our data collection instruments, our, it was sort of a dress rehearsal for the main study, and the sorts of results I want to share with you are things which will either tell us our projections were good or our projections were poor, and some of the things we might expect to find during the main study.

I want to say at the outset, we're quite pleased with the results. Everything went quite well. We think we can expect a successful main study. The only thing that was negative that came out of our pilot study is that tracing, locating our study subjects, cases and controls proved to be more difficult and time consuming and expensive than we had anticipated.

However, our final location rate for the pilot sample turned out to be quite acceptable. If our main study location rate is maintained at that level, I think we will be

quite acceptable. We started out with two hundred fifteen cases and controls, a hundred and thirteen case families and a hundred and two control families. We began tracing these families in December of '81, began interviewing those who were located in January, continued interviewing through the end of February '82, and stopped interviewing at that time.

Tracing continues today and we'll continue working on tracing of the final sample until we've exhausted all possibilities for finding them. It's important that we do this so we can evaluate and modify our tracing procedures as our results suggest we do.

As of the end of March we had found eighty percent of our pilot sample, and as we had found at least one parent as of that time. We have found another seven percent at a confirmed address with an unlisted phone number or no telephone at all. This is important because our study is a telephone interview study, and the residual is fourteen percent that we have not located, about thirty families.

As of the end of February when we suspended interviewing, interviewing was suspended because our, we couldn't keep up enough case load to warrant keeping interviewers on the staff at that time. We had attempted to interview a hundred and twenty-five mothers and we completed interviews with a hundred and twenty-one. Two of them were outright refusals, and

quite encouraging if our main study refusal rate remains at that very low level, and the other two that were not completed were interviews where we have appointments in the future that could not be completed for one reason or another.

We completed interviews with ninety-four fathers. It is fewer than the mothers. We're actually quite pleased with this. We had expected some trouble in doing this with the fathers. We didn't think that they would be patient enough to sit through with us, and it turned out that they did. I think our refusal rate was somewhere on the order of two or three percent for fathers. We had a more difficult time locating fathers than mothers.

Just a few items of interest which will indicate probably what we will wind up with in terms of the types of people we're able to locate and interview. The pilot sample: about three quarters of the mothers were white, which is roughly what we should expect based on the racial distribution of births in the Atlanta area. However, the men that we managed to interview were ninety percent white. So we had trouble locating black fathers.

The men that we interviewed were also quite well educated, almost thirty percent of them were college graduates with one or more years of graduate education. Roughly seventy percent of the mothers that we interviewed lived with the father of the index baby. Thirty percent of them did not live

with the father of the index baby. On the other hand, ninety six percent of the men that we interviewed lived with the mother of the index baby. So in other words where the father and mother separated, we had some difficulty in finding the father.

Roughly forty, forty-five percent of the men, of the fathers of these babies,had served in the military and of those a quarter had served inVietnam, so that roughly ten percent of all the study families, fathers had served in Vietnam. This is an important figure because we had based our sample sizes, particularly of the controls, on a ten percent rate of having served in Vietnam.

Two last things involved answers that mothers and fathers give to essentially the same question. We had thought initially that it would be important to talk to both mothers and fathers, feeling that there are some things that fathers can tell us with more accuracy than mothers can, and vice versa, and I just want to share with you answers to two questions.

There were about ninety families where we interviewed both the mother and the father. Some families we interviewed only the mothers. Some families we interviewed only the father, and about ninety where we interviewed both the mother and the father. One of the questions was whether the pregnancy which resulted in the index birth was a planned

pregnancy and out of that ninety, thirteen of the mothers and fathers gave different answers. It surprised us insofar as out of the thirteen, ten fathers said that the pregnancy was planned whereas the mothers said that it was not, whereas only three of the fathers said no and the mothers said yes. We have this inbalance here, obviously not some sort of a random type.

There are certain things, this being one of them, where we would probably take the mothers' word on it. Another one which surprised me a bit, even more than the planned pregnancy question, was the question whether the father was in the military or not, and we found that seven fathers said that they had been in the military where the mothers said that they had not, just in the military, whether the man had served in the military or not. And there was one where the father said that he had not and the mother said that he had.

Well, again, this emphasizes the importance of talking to both parents when we are dealing with issues that are, where you would expect the mother and father to have different ideas about things. I think that's about all I have to say, besides answeringany questions.

DR. SHEPARD: Thank you very much Dr. Erickson. Are there any questions of Dr. Erickson?

I guess I would have one Dave. Do you plan to treat the data differently in those cases where you don't have both

parents interviews, or an interview with both parents? Will you sort out those and the ones where you get both the mother and the father as being much more accurate and more complete than the ones that do not?

DR. ERICKSON: Yes. I think the hardest thing for us to do will be to deal with these discordant answers. I think when you have a question of whether the man has been in the military or not, I think we would generally take the man's word for it, but there may be other things where it's not so clear, and that's an issue which, unfortunately, I have no answers for, at the moment, as to how we're going to handle it.

I think that what we can expect is probably have interviews with only eighty percent fathers as we have mothers, and we will probably treat interviews with the mothers as a separate analysis; and those where we have both the mothers and fathers as a separate analysis. I doubt that we'll have enough fathers in the absence of the mothers to make much sense of it though.

DR. SHEPARD: Dr. Moses.

DR. MOSES: I'm just curious. I realize this question always comes up, but how can you be sure it's the father. I mean do you think that's going be an important problem?

DR. ERICKSON: Yes, it's an important problem.

I have heard rates of non-paternity up to fifteen percent, I don't know how, based on blood groups and things like that, I'm not sure whether that's a good figure or not. It's certainly not an insubstantial proportion whatever it is. All we can do is ask, of course. We're not in the situation where we can do blood tests and at least rule out paternity, so all we can do is ask the men and women whether. What we do not specifically ask is John Jones the father of Janie Jones, but we do ask the mother whether the father of record is the father of all of her pregnancies and vice versa. We ask the man whether he is father of all of the pregnancies of the women, so there is an opportunity to say this really isn't.

DR. MOSES: Are they interviewed separately? I mean you might get different answers if, you know, they're not in the same room.

DR. ERICKSON: Yes. We would prefer that, but I suppose in the majority of the cases the interviews are done when the father is not around, but we do try to keep a record of when the mother has asked the father for help in remembering things and vice versa. I would say it is not an easy thing to ensure. We certainly do not feel at liberty to ask the mother or the father to be sure the spouse is not around when the interview is done and I just don't think there is any practical way around it.

DR. SHEPARD: Any other questions or comments? Thank you very much Dr. Erickson. For those of you who are not aware of this, I just want to point out for the record that the funding of this effort is being provided jointly by the Department of Defense, the Veterans Administration, and the Department of Health and Human Services. So it really is an inter-agency study. The principal investigator is Dr. Erickson and he's doing I think a fine job. We're all very pleased with the project and commend you for your efforts Dave.

AIR FORCE HEALTH STUDY (RANCH HAND)

Next I'd like to call on Dr. Young again to give you a little bit of an update on the status of the Air Force / Health Study, formerly known as the Ranch Hand study. There's been a shift in terminology here, but there hasn't been a shift in the study. We're calling it by a slightly different name, but that's what it is, and he'll tell you about that study and a recent trip that some of us made to Texas to get a first hand view of the progress out there.

DR. YOUNG: You know when you conduct epidemologic studies there are many factors that you have to take into consideration. Very frequently you can go to people that have already conducted the study or have been working on a particular study and learn some of the lessons that they had to learn the hard way, and it was a recommendation from me that Dr. Shepard and some of the VA folks go to

of Aerospace Medicine
San Antonio and meet with the School/ and to talk with
Air Force Force
those/folks about the Air/ Health Study and try to pick
up some of the lessons learned in launching into a major
epidemiologic study. So from the 4th to the 6th of May we
did go to San Antonio. There were six of us including
Richard Christian. Mr. Christian from the Department of Army,
the record specialist, because the Air Force folks have had
to worry about records, record reviews, the construction of
an exposure index. We wanted to try to get our people that
would be working in that area interfaced with the Department
of Air Force personnel.

this
As of / date, the Air Force has completed about seven
hundred and fifty of the physical examinations that are being
conducted. Those examinations are being conducted at the
Kelsey-Seybold
Clinic in Houston, Texas, and that is seven hundred
and fifty of the twenty four hundred, twelve hundred indivi-
duals that served in operation Ranch Hand and their matched
control, individuals that served inVietnam but were not
involved in the Ranch Hand program.

The questionnairephase of the Air Force study is well
under way. Thatquestionnaire phase is being administered
by Harris Polls, Lou Harris Incorporated. They've completed
about eighteen hundred of the twenty-four hundred question-
naires. The last six hundred are those very difficult ones.
They're located throughout the world. There are a whole

group in Europe. There are a group even in Africa, and we've had individuals from Harris Poll out traveling the world to pick up the rest of the Ranch Handers and their controls that were not readily available.

The questionnaire phase, the administration of those questionnaires is to be complete, assuming everything goes well, by the end of this month. The physical examinations, they're taking about sixty-four a week, so we're looking at completing the physical examination phase in the end of September or the end of October, in that time frame.

The third phase of the Air Force study is a mortality analysis, and that particular phase is well underway. They've located all the death certificates. They've made an examination of them. We're hoping that information will be released within the next few months, so things are moving very nicely.

When we got there, they gave us a quick overview of the various studies that they were conducting portions of the Air Force Health Study, and then they went into some of the lessons learned that would be of interest to the VA.

To give you some idea of the things we picked up from them, the issue of confidentiality, that was a heavy issue that they emphasized in terms of the questionnaire and the physical exam components. They re-emphasized to us the importance of keeping that in a confidential manner.

We talked about the issue of stipends and will that help enhance participation. The issue of peer review, how extensive should it be, how extensive was it for the Air Force. The value of the oversight committee. The Ranch Hand folks have six individuals nationally recognized that provide oversight to the conduct of the study and the Air Force folks praised them very highly. A lot of the ideas that come out of the oversight committee have been very valuable.

The conduct of the pilot study, the best way to conduct it. The release of data to the individuals and to the press, all issues that the Air Force folks have had to look at. The importance of coming up with a very strong audit trail for scientific decisions, and for quality control of the work.

To give you some idea, the Air Force is looking at some thirty five blood parameters and the importance of having quality control for those analysis is very critical to them. Slight variations in how people handle them in the laboratory can impact the quality of the data, and so they've had to standardize every single aspect of it. Likewise, the standardization of the physical examination. We had a chance to go to the Kelsey-Seybold Clinic in Houston and to see how they handled those individuals coming in for the physical exam. I can tell you I've been involved in the study, but I was very impressed how personalized they got in the conduct of that physical exam.

It's a thing that very much concerns me from the point of view of the Veterans Administration conducting a study of say eighteen thousand, how difficult it will be to personalize each exam. For the Air Force with twenty four hundred and the team that they have selected through contract to Kelsey-Seybold has just been very impressive in just how personalized the examination is being made.

The importance of a strong biometric component was emphasized. If you're going to collect data, you must know how you're going to analyze it. That was strongly emphasized for us. When you take data on a questionnaire, you have to be able to relate it back to some method of analysis. Not only do you have to be able to analyze the data, but you have to be able to validate it, so when you ask a question on a questionnaire you have to be able to go out and validate that answer.

If you ask an individual how many children that individual has and he says five, then you want to go out and try to find five birth records to validate it. So for the Air Force folks going out and finding all of the records on twenty four hundred, it is a massive job.. simply a massive job, and I look at us to do it for eighteen thousand. It's no wonder we're talking about many years. It will be a very massive job.

The preset of the statistical framework was very very

important, and they emphasized to us that our exposure index will have to be very carefully done,and we're going to have to follow very carefully that exposure index from the very first individual we select all the way through to the last individual.

We talked about the kinds of forms you needed to have to run the operation and that was emphasized. A blind assessment in terms of the physical examination being conducted / was also discussed. The physician does not know whether he's examining a Ranch Hander or a control, and it was very difficult for physicians / to adjust during the first few dozen people that went through. It was difficult for those physicians not to want to ask the kind of questions they would normally ask in conducting a physical exam, but we literally gagged them. We said do the examination, but don't ask any questions related to Vietnam and service /and so on. So it was quite a lesson for those physicians who are working in the project.

The Ranch Hand researchers / gave us some very interesting ideas as to what sort of key personnel would be required(in their view)for the VA in actually setting up and monitoring the an study. They went through and told us what kind of /epidemiologic specialist, what kind of biostatistician they think would now be important. The record specialties, they talked about that.

It was great having Dick Christian along because he was able to pick up that information and to take that back to his group. The handling of the study subjects was the last issue we brought up. The Air Force folks emphasized how you must handle them. You want to handle them as though every one of them was a VIP. That's how you're going to get the individuals to participate and that's how you're going to get the individual to come back for the next round. If that individual feels that he's a very important person and that he's needed to make the study work, then he'll participate, and that's something we in the Veterans Administration are going to have to really focus on I believe.

Well, I won't take any more time. That's a very quick overview of some of the things that we picked up and some of the interactions we had.

DR. SHEPARD: Thank you. I think it's important to point out that because of the treatment the individuals are receiving, and I can attest to the very high caliber and high quality work that's going on, they have a phenomenal participation rate. I think I'm accurate in quoting the figures, they have a ninety-seven percent participation rate in the ninety-four percent participation rate in the physical examination. This exceeded their wildest expectations so it attests to how carefully the study has been put together and particularly the interface with the

individuals that's been done.

DR. YOUNG: Many of you will remember that we had a lot of heavy discussion a year to two years ago about participation and how do you get pilots to come in and participate; how do you get folks that are not too pleased about the military to come back in to participate; and indeed the approach that the Air Force has taken has been responsible for bringing those individuals back in to participate. They're doing it in little groups, thirty-two per group during the examination phase, and the individuals are a mix of both control and Ranch Handers. An interesting thing that came out of those little groups -they're together for four days. They've all come back and said when you call us back for the second round of examinations, call us back as the same group because we've established rapport with our own little group. They don't want to be broken up and put into new groups. They want to come back as the same group next time. That tells you something about the rapport that is being developed.

DR. MOSES: Can I ask just a quick question about the physical examination that you discussed. Is that confirmed by another physician and if there's a discrepancy, I'm thinking perhaps of something like liver size for example, or whether -- -- I'm just curious how the decision, because we've gone through this, I'm curious how they handled that.

DR. SHEPARD: We asked similar questions obviously. This falls into the area of quality control. The physicians doing the examination are carefully instructed that if there's any question about something, that it be checked out.

In the case of puzzling conditions consultations are sought.

There are two physicians, more than that, there's a generalist. I think all of the physicians actually doing the examinations are Board certified in internal medicine. There's also a neurologist who does a detailed neurologic examination, and the data from those examinations are then recorded / as are, of course, the laboratory studies, chest x-ray and so forth.

At the conclusion there is a diagnostician who puts that all together, reviews all the data and has an interview with each of the subjects. He goes over the record, the findings, whatever, with the individual so that each member of the study, both the / Ranch Handers and the controls, have the benefit of having all of that explained to them by a physician.

DR. MOSES: That wasn't quite my question but I can discuss it with you later. I was much more concerned about a positive finding, for example an enlarged liver. We've looked into this ourselves. Some doctors you can guarantee are going to find two or three centimeters larger

than others, and in terms of quality control I'm just wondering how they're handling that in this particular study because some of these findings could be quite important to the output you're looking for, how this is explained, what's happening at the laboratory. I'm concerned about what's happening with the physical exam, just curious about how they are handling that.

DR. SHEPARD: Some of that standardization is being provided by the fact that there are, I think, only two physicians doing all the examinations, two generalists, so there is some standardization in that regard. The same neurologists are --

DR. MOSES: What neurologists? One neurologist?

DR. SHEPARD: For each examination I think there's a team of three neurologists that have been involved in the entire setting.

DR. HOBSON: Specifically, to answer your question, my understanding was that the physical exam was done by only one physician so that there would be only one report on liver size and they didn't run into that difficulty. On the other hand, with only two examiners it was very easy for them to standardize. I think there is a possibility of error but I really don't know how you get around that very easily, as you found.

DR. MOSES: Well, what we do on our study when something is really important, if say a liver study, it would have to be done by another physician and if they both agree

then it is recorded, and if they don't, then a third person comes in. We think it's very important for certain of these things. I was just curious. It was not my impression that they did not use that technique. You'd be surprised if you compare doctors and have them -- on the same liver, how much variation there is on the centimeters.

Participant: You started your discussion by emphasizing the importance in the confidentiality of questionnaires./ Precisely what did you mean by that?

DR. YOUNG: The actual questionnaire itself, the Air Force has been very tight about who sees the questionnaire. For example, I've been a member of the team but I have not seen the questionnaire. They have kept it very tight. Likewise the physical examination, the data for the physical examination has not been distributed. They have kept it. They have not shared it with anyone outside of the team, the very close team members, and with the/ Kelsey-Seybold Clinic of course, the Lou Harris Polls. But they have felt very strongly/ about the quality of the data that would be gathered/ and its being influenced by the release of the questionnaire and the physical exam prior to its administration. Now that's their opinion, and they have been successful at doing that.

They do plan to release both the questionnaire and the

physical exam at the completion of the administration period. So they will be released and they'll be released prior to the conduct of our study I suspect.

DR. SHEPARD: Any questions? Dr. FitzGerald.

DR. FITZGERALD: I'd like to carry that confidentiality another step further to another field, and that is that there have been expressed concerns by individuals who are still in flying status that their future flying status would be threatened if (1) they participated in the examination, and I'm surprised at your ninety seven percent participation because of that; and (2) as to whether that information would ever be released to threaten their flying status in the future. How would they handle that?

DR. YOUNG: They have been very forthright with the participants in the outbriefing. The doctor does in fact give them a very complete review of their health status and if they find any significant findings then they do inform the individuals. The individual's informed when he first gets there that that information will be provided to the appropriate authority, so they are aware of it. They're participating despite knowing that information.

It is interesting Dr. FitzGerald that some of the ones that are not participating are pilots that in fact, although they answered the questionnaire they didn't show up for the physical exam. Now there's only a few of them

participate in the study
that did not /so there are/only a few that are very worried about study participation and its impact on flying status.

DR. FITZGERALD: I've had contact with a few in this regard that's why I was concerned about it.

DR. YOUNG: But it's only a few.

DR. FITZGERALD: I was just wondering whether the, it will be an increase in declining to participate as you get further along in the exam.

DR. YOUNG: Well the/way the Air Force, is conducting the study, really emphasizes the continuation aspect, the follow up phases, The VIP treatment, for example,/helps but/I think also that they've tried to build a sense of interest within the people/(study participants) to keep them going.

There is a mechanism for replacement in terms of the control, a statistical mechanism they designed, and I can't go into it, I don't know that much about statistical requirements, but they did come up with a replacement concept that was peer reviewed through the protocol process, and they do have a way of replacing controls. They do not have a way of replacing Ranch Handers though. It is a study that is to go on for twenty years and the big concern now for the Air Force is how do you take all of the data, all of these observations at this point in time and assemble / it in a manner that somebody twenty years from now can take the information and

evaluate it. So the data collection systems have to be accurate, have to be correct from day one, and they have to be followed all the way through to the end / since as these investigators down there pointed out to us, they won't be there probably when the study is complete. Some of them will be retired or off in some other job and it'll be for some other principal investigator to come along and pick it up in those years.

PUBLIC INFORMATION AND EDUCATION PLAN

DR. SHEPARD: Any other questions? We'd like now to call on Mr. Larry Moen from our Division of Public and Consumer Affairs to give us an update on the public information education plans. Larry.

MR. MOEN: Thank you Dr. Shepard. The office of Public Consumer Affairs, in close cooperation with the Agent Orange office of research and education and Dr. Shepard's environmental medicine group, is undertaking to increase the flow of information on the matter and progress related to Agent Orange to the public and to Vietnam veterans specifically and to the news media.

In the first stages of our information and education program, we are going to the Agent Orange registry with the idea of conducting a direct mail campaign, if you will, to those members who have shown an interest in Agent Orange by coming to our medical facilities and receiving the physical examination.

We are computerizing that mailing list, the Agent Orange registry and at the end of May we intend to send in a letter along with the newest and most current brochures or fact sheets on the subject of Agent Orange.

Following that effort, we will then, and have already run a computerized list of our compensation and pension and education rolls to come up with the Vietnam era veterans to whom we intend to send a letter and from that we will distill the Vietnam veterans and put them together with our Agent Orange registry list so that we have a mailing list of Vietnam veterans who would have shown an interest in receiving information on the subject of Agent Orange.

As a matter of interest, we will be also sending to that first group the first two pamphlets or at least the new and current pamphlets, one which was done in April, Agent Orange Information For Veterans Who Served In Vietnam. It's general information. In May we released another pamphlet on Agent Orange which deals specifically with Public Law 97-72 and that, of course, is the legislation that was passed in November which allows the Veterans Administration to treat veterans who come to our hospitals and medical centers who feel that they have been exposed to Agent Orange and who have conditions which the doctor determines is due to Agent Orange exposure.

We have another pamphlet that is due out the first part

of June. It's a question and answer pamphlet about eight pages of the typical questions that we receive in the Veterans Administration on the subject and to which we do have answers. We all know that there are many questions we don't have answers to, but in this pamphlet we at least attempt to lay out answers to those questions that are most frequently asked of the Veterans Administration.

As follow on to that, we intend to provide a more in-depth publication which will detail the various scientific research efforts which are on-going in the federal government.

Also, it is our intention to publish quarterly a digest of Agent Orange information which deals primarily with up-dating the progress of these various scientific efforts that are ongoing. All those people in the Agent Orange Registry as well as those on the mailing list would receive it along with the veterans service organizations.

As a follow on to that, we have plans for display and franked card return mailers at all VA facilities. We are planning to design print media public service advertisements for veteran service organizations publications with the inclusion of tear-out mailers, and print and broadcast public service announcements directing interested parties where to write

call for more information on Agent Orange. That's a brief review of our efforts to increase the flow of information on this subject.

DR. SHEPARD: Thank you very much Mr. Moen. I appreciate those comments. Are there any questions for Mr. Moen? He and his office have done a bang up job, I think, in pulling this information together and putting into a format suitable for distribution and the process for doing that.

I apologize for the temperature in the room. I had hoped it would have been a little warmer. I hope it isn't affecting our thinking in any way. I'm about to experience some hypothermia and I think maybe we ought to take about a ten minute break and warm up.

(BREAK)

REVIEW OF PROPOSED PROTOCOL

DR. SHEPARD: I think it would be appropriate at the present time, I think most of the members of the Committee are back in the room, to open a discussion on the subject of the review of the protocol. I would like to propose that we meet, reconvene this afternoon, in closed session, and we have copies of the protocol available, the full protocol available for members of the Committee to actually sit down and root through that. We, here in the VA, view that as a very desirable and needed effort, so I would like to recommend it strongly to the Committee, but I'd also like to solicit

comments from the Committee in regard to that since it is a Committee activity I think it's appropriate that any members feel free to express their opinions on the pros and cons of holding this closed meeting this afternoon.

DR. MOSES: Well I'm very much in favor of it if you want my opinion.

DR. SHEPARD: Good. Thank you. Dr. Moses says she's in favor of having such a meeting this afternoon. Dr. Murphy?

DR. MURPHY: Well, I wonder whether, what we expect to achieve by this. If as Dr. Young indicated they aren't aware of questionnaires and details of that study they're conducting, will this Committee be made aware of the details of this? Is that the purpose?

DR. SHEPARD: Yes, it is. I though I tried to make it clear that we will have the full protocol here for the members of the Committee to review in closed session this afternoon.

DR. ERICKSON: Well, I guess I may as well register my opinion of dissent. My opinion as an epidemiologist is that it's not necessary to keep the questionnaire confidential. I recognize that there are differences of opinion among epidemiologists and I respect the UCLA group, but I happen to disagree with them, and I personally think that in a short session it would not be possible to make any adequate review

of thequestionnaire, which judging from the table of contents is a hundred or two hundred pages long. I don't think that much can be accomplished and I think I would not participate in such a meeting since it would give tacit approval to the procedure which I disagree with.

DR. SHEPARD: Okay. In regard to your first point of what would be accomplished, It is not my expectation that a one session meeting this afternoon will answer all the questions and solicit all the comments that should flow. What I would like to do is to make sure that all members of the Committee who would care to see the full protocol and make such observations both today and at a later time that they would care to do. I think it's an important part of our review process.

I appreciate the major difference of opinion that exists among recognized epidemiologists on this issue. I don't pose as an epidemiologist by any stretch of the imagination so it's a little difficult for me to adjudicate this question in any way at this time. It seems to be two different positions. Yes?

DR. MURPHY: Well, I wonder if you have experts in epidemiology beyond those you have here. Have you utilize those people as consultants to review these matters?

DR. SHEPARD: Yes.

DR. MURPHY: And that to me is the kind of thing, that kind of detail has to be questioned and evaluated. I frankly don't know what I could do with that questionnaire.

DR. SHEPARD: We have done precisely what you suggest and we've come up with about a 60-40 split on the question as to whether or not questionnaire and data collection instruments such as for a physical examination should be held confidential.

DR. MURPHY: Do you have people who have looked at the questionnaire that you are dealing with?

DR. SHEPARD: Yes sir, otherwise they wouldn't be able to make a rational judgment in that respect.

DR. FITZGERALD: I think I would like to respond also Dr. Shepard. I first of all want to thank you for having the session this afternoon because I think it's in response to the objections that some of us raised at previous meetings, and our objections were based upon the fact that there are other committees involved in Agent Orange who have been allowed to see the full questionnaire, and have been requested to maintain confidentiality of the questionnaire. It seemed inappropriate to me that if we were going to be an advisory committee to the VA that this specific committee would not be given the same perogatives as the other committees which indeed brought up the question of the validity and the

desirability of maintaining this Committee. My greatest concern was the interpretation of such action in the past and that any doubt as to the validity of the study that would be raised even though unwarranted would be a serious hazard to the acceptance of the outcome of the study in the future and that basically was what I had to say.

DR. SHEPARD: Thank you. Any other members of the Committee wish to comment?

DR. HODDER: I think I agree with what Dr. Erickson has said in terms of what would jeopardize the study. I don't think the questionnaire, at least in a group like this, the knowledge of the questionnaire should not jeopardize the study. I think the only thing that would jeopardize the study is knowledge of the exposure index because that is the starting point. If you don't know whether you were or were not exposed, you don't know which way to bias your answers in the questionnaire. I do think that there is a reason why the people advising on the Committee ought to see it. I think the amount of information that will be collected on that questionnaire will have a major impact on how big the study is going to be, how much quality control needs to be done on the study and also ultimately what analysis ought to be done on the pilot data. If you have a questionnaire that's huge there needs to be a lot of internal validity checks in it and there also, it seems to

me, needs to be a lot of pruning before you get into the major study. I don't see how we could advise very well on the transition of the pilot study to a major study if we don't know that.

DR. SHEPARD: I would certainly agree with that Dr. Hodder, and, it seems to me, that is among the more pressing and persuasive arguments that this has to be reviewed. Ultimately the decision, it seems to me, rests with the Veterans Administration as to what the protocol will be and essentially how it will be used or what will be the protocol. We have solicited the advise of a number of peer review groups, also the Office of Technology Assessment of Congress, the science panel and the Agent Orange Working Group, and now the National Academy of Science, and the VA Advisory Committee, but clearly the bottom line, the buck will have to stop at the VA as to exactly what is going to be done because it is a Congressionally mandated study, the mandate being given to the VA to conduct the study. So we clearly need the input of appropriate review bodies such as yourselves to make some hard decisions or help us make some hard decisions in terms of the extent, the detail of the questionnaire, how the data is going to be handled and all the things that you so ablely alluded to.

So, are there any other comments? I would then as Chairman call a meeting, a closed meeting this afternoon to start at 1:00 p.m. in this room.

hopefully in a better environmental state.

ADVISORY COMMITTEE: FUTURE/COMPOSITION

The question had been sent out to the members of the Committee concerning the future of this Committee regarding its composition, its activities and so forth. Several people have from time to time suggested that it might be appropriate to have an advisory committee composed largely of individuals who serve as representatives of service organizations rather than as a scientific advisory group.

There clearly needs to be some scientific advice provided to the VA and we wholeheartedly solicit that. Whether that should be conducted in this atmosphere and framework or whether this Committee should serve primarily as an advisory committee on policy and the methodology for bringing the concerns of the veterans to the VA is still an open question. I personally have had various feelings and attitudes on the subject and I guess after having looked at this myself have come out with the feeling that we probably ought to continue this Committee pretty much as it exists.

On of the problems, of course, and one of the issues that has stimulated this kind of thinking is that some scientists who have served as members of this Committee have appropriately expressed to me and others that the advice of this Committee is really not solicited, that this is not

strictly speaking an advisory committee and that it is a policy discussion or information gathering committee but not really advisory. That is not, I don't think, wholly justified criticism. I think all of you will agree that there have been times when we have in fact solicited your advice on specific points. So I have now come down to the opinion that we ought to, subject to the members willingness to serve in this capacity, that we ought to continue pretty much along the lines that we are, maybe with some strengthening in certain areas. I would like to now open that up for discussion and receive your opinions and views. Some of you have commented on that in letter to me and we appreciate those comments, but I would like to afford the opportunity for that kind of discussion at this time.

Would anybody like to express an opinion? Are there any members of the Committee who have any suggestions as to perhaps a change in the format or a change in the agenda or a change in the way we do business? Dr. Lingeman?

DR. LINGEMAN: It is my opinion that you are not required to take our advice. I serve on other advisory committees and we are only asked to advise, not to dictate, opinions. The VA has the ultimate responsibility. Therefore I am as a member of the Committee satisfied with the current system. As I suggested in my letter to you, perhaps specific issues

specialized
need to be dealt with by sub-committees and I still feel that there are certain issues that are much too complex for this
everyone on Committee to grasp that need to be dealt by experts
with. For example, we have there are but epidemiologists on the Committee, I think there is a need for separate sub-committee of epidemiologists to advise the VA. This was alluded to earlier. Does the VA have a Department of Epidemiology?

the other VA advisors
I have never seen a list of who are. I don't other ist
know who your epidemiolog advisors are.

DR. SHEPARD: Yes, that point's very well taken. I think that you allude to the fact that we have epidemiologist advisors. There is no, to my knowledge, epidemiology advisory committee to the VA. This advice comes from people that sit on this committee, as individuals.

There are some epidemiologists who serve as

of the
members of the science panel/Working Group. The Office of Technology Assessment has from time to time called upon epidemiologists to provide advice and input to their deliberations. So we still do not have a specifically designed committee on epidemiology per se in the VA.

DR. MOSES: Is there an epidemiologist on the Agent Orange Working Group? Is there an epidemiologist on that committee?

DR. SHEPARD: Dr. Carl Keller from NIEHS serves as a member of the science panel and he is an epidemiologist. There are other people. The term epidemiologist is not a very precise term, or perhaps there are many aspects of the science of epidemiology. Dr. Hodder may disagree with me, but it sometimes difficult to define what exactly an epidemiologist is. So, as I say, there are many facets to that skill or that group of skills. There are medical epidemeologists. There are biostatistical epidemiologists. There are people who specialize in infectious disease, for example, who consider themselves epidemiologists, and I will be the last to quarrel with their qualifications in that term, but I think it's accurate to say that there are varieties of epidemiologists. Dr. Erickson?

DR. ERICKSON: Well, it seems to me, I agree with Dr. Lingeman how to get more epidemiological advice and/as you were ticking off the list of organizations used to obtain

epidemiological consultation, it occurs to me that you have no non-federal people which would seem to me to be important, no non-federal employee epidemiologist, and it would seem to me to be important to obtain advice from the academic community and it should be relatively easy to do that by approaching one of the epidemiological organizations, the Societies for Epidemiological Research, the American College of Epidemiology, the American Epidemiologic Society, have in the past I believe assisted in the formation of advisory groups on issues like this.

DR. SHEPARD: I think that's a point very well taken. Of course the National Academy of Science will have non-federal epidemiologists serving as their panel / so we will get some non-federal input from them, and Marion Moses is not a federal employee.

DR. MOSES: Not yet.

DR. SHEPARD: Dr. Woodward is now a federal employee In his capacity as a distinguished physician for the VA he is considered a full-time VA employee. That is a relatively recent event. Dr. Suskind of course is not a federal employee.

Did you have something else you wanted to say?

DR. HODDER: No.

DR. SHEPARD: Okay, having settled that matter then, if any of you have any specific recommendations in terms of both a committee or membership or makeup of a committee for

our oversight, for the epidemiological study or other members that could serve as advisors to the VA, please feel free to give those names to me.

I think we have quite a number of questions here from the audience and therefore I would like to get into that portion of the agenda unless the Committee has some other issues that they want to bring up. Yes Dr. Murphy?

DR. MURPHY: I'm not quite sure I understand the co-chairmanship concept that was mentioned earlier today. What does this mean in terms of the Committee operations?

DR. SHEPARD: Mr. LeVois and I would simply share the responsibility of chairing this Committee.

DR. MURPHY: It would not change the type of issues brought before the Committee.

DR. SHEPARD: No.

DR. MURPHY: Not dilute your effectiveness as the Chairman.

DR. SHEPARD: I hope not. Whatever that may be. No, I just would like to say that Maurice and I have developed a very good close working relationship,and I think that this has been a very fruitful effort. I am in no way threatened by his co-chairing this,and I would welcome that sharing of responsibility with him.

COMMENTS AND DISCUSSION

All right. We have quite a stack of questions here and I will feel at liberty to refer them to any members of

the Committee unless they are specifically designated to a particular individual.

The first one that was submitted comes from Mr. Milford from the National Veterans Law Center and reads as follows:

"Studies from Sweden report a five to six fold increase in soft tissue sarcoma among workers exposed to a dioxin contaminated herbicide. Last month the Government's National Toxicology Program found that dioxin is a carcinogen in one species of animals. In the May 6, 1982 issue of the New England Journal of Medicine three cases of soft tissue sarcoma were reported in Vietnam veterans who served in Vietnam In light of this overwhelming evidence of the relationship between dioxin and a rare form of cancer, does the VA have any plans to change its compensation policy to award benefits for this form of cancer as related to Agent Orange? If not, how much evidence would be necessary to compel the Agency to award benefits for any disability as related to Agent Orange exposure?"

Let me just say from the outset that this Committee does not in itself deal with matters of compensation per se. That isn't to suggest that the Committee could not appropriately make recommendations to the Administrator dealing with areas of compensation, but that is not principally why this Committee

was organized. So in terms of does the VA have any plans to compensate, we've not dealt with that. So as far as I know the Committee doesn't have any position on that, at least not based on any previous decisions. However, I would certainly welcome any comments from members of the Committee on this matter. Well, let me just leave it at that. Okay, not hearing any comments I would like to just mention a little bit of what I have been doing in the last few days subsequent to the New England Journal of Medicine letter to the editor. I have a few copies of that in the event any members of the Committee have not seen that. Have you all seen it? I'll circulate it and then you won't have to say whether or not you've read it.

This was in the, I think, May 6th issue. Basically what this article refers to is three Vietnam veterans who were found to have soft tissue, thoracic soft tissue sarcoma. I presume the report having come from Emory University School of Medicine we know that two physicians who authored this letter are in fact full-time VA employees, and one then presumes that these were veterans who were diagnosed, although it doesn't say so specifically, diagnosed in a VA hospital in Atlanta. I don't know that that makes any difference one way or the other, but let's assume for the moment that these individuals have been seen by these three physicians, two of them in 1979, and one in 1981.

I've been looking, Dr. Hobson and I have been looking in the National Center for Health Statistics, the National Cancer Institute reports on incidents of cancer of various types and this is a very complete compendium of health statistics and in that there are tables that allude to the incidence of certain types of illnesses based on age, sex, race and geographic distribution, so we were able to determine the incidence of soft tissue sarcoma / in males between the ages of thirty and forty. As a national average of all races, the incidence is 1.5 per hundred thousand males. That's the annual incidence of new cases.

One assumes that 2.4 million veterans served in Vietnam one comes up with a twelve year span which is approximately the mid-point of the Vietnam era to today of some expected four hundred thirty cases of soft tissue sarcoma / in a group of 2.4 million. That's not making any analysis, that's just extrapolating from that incidence ratio. So that it's my putting together what I've been able to find out about this. One would expect somewhere, as I say, somewhere in the vicinity of four hundred and thirty cases of soft tissue sarcoma / over the last twelve years in this age group and so that I don't find it particularly surprising that in a metropolitan area as large as Atlanta one would find three cases of soft tissue sarcoma. The thing that we haven't been able to find is what the relative proportion of intrathoracic soft tissue sarcoma / is as

compared to the whole issue. In other words what percentage of those four hundred and thirty would one expect to have arising in the chest. The chest has a lot of soft tissue in it, so it's not, I would think it would not be particularly out of line.

Do any members of the Committee have any thoughts on that subject? I've asked Dr. Lingeman to look at this piece of paper that I've put together in the last couple days and I would be happy to have comments from others. I didn't bring enough unfortunately for the entire Committee but if any of you would like to glance at it to see if you have any impressions as to its validity.

We also as you know over the years there have been a number of letters to the editor to Lancet / the British Journal, the British counterpart, and I expect the New England Journal, it's also a weekly medical journal alluding to the relationship of soft tissue sarcoma / to herbicide exposure. The Swedish studies, I'm sure you're all aware, make that same kind of observation. I think it's accurate to say that no reputable scientist has at any time that I'm aware of concluded that there is a definite cause and effect relationship between exposure and the development of these problems. / It simply is a correlation of factors which exist, two factors which exist in a group of individuals that have been studied.

Does anybody have any information on cause and effect?

Is anybody aware of any persuasive evidence that there is a cause and effect relationship between exposure and the development of soft tissue sarcoma?

So I think that although it's an area that requires research and case control studies are currently underway in the State of New York. The National Cancer Institute is undertaking a case control study to forward using tumor registries, looking at the possibility of relationship between other herbicides such as 2,4-D / so that the issue is under, I think, a fair amount of study. I hope that our epidemiological study will be of sufficient quality so that if there are unusual tumors that they will be detected so that in the next few years I hope we'll have some scientifically valid answers to these questions, but as of the present time I think I would perhaps take issue with the suggestion that there is overwhelming evidence of the relationship between dioxin, overwhelming evidence of the relationship in the sense of a cause and effect relationship. I question that there is overwhelming evidence. Yes, Lew?

MR. MILFORD : Would you like to follow up on that a second.

DR. SHEPARD: Sure.

MR. MILFORD : The point of the question obviously was to go to the standard of proof that may be required for the Agency to determine that there is some relationship

to award benefits. What I hear implicit in your answer is that it will be necessary for there to be results from the government sponsored study before there will be any determinations to award or not award benefits, and if that's true or not, I would like an answer to that, and if it's not true, then the question still remains what the standard of proof will be, how much evidence may be enough and if there, you have a combination of epidemiological studies, laboratory findings and -- case studies as being insufficient to find a cause and effect relationship at least sufficient to award benefits, then how much will be enough.

It's my understanding that in any court of law that's probably sufficient at least to go to the jury to decide whether there's a relationship. So I guess the remaining question is whether that's a proper subject for this panel to consider. Apparently no other part of the Agency is considering that compensation question so it seems to me that it would be an appropriate issue for this panel to discuss.

DR. SHEPARD: I did not mean to imply that we are simply looking at federal or government studies.

Obviously many of the reports are not government, U. S. Government studies. At any rate we would very much welcome any studies that are being done by any scientific group as providing that evidence. You raise some legal

question that I certainly do not feel competent to address in terms of sufficiency of proof and sufficiency of evidence and how that is handled in the courts. I just don't have any expertise in that area so I really don't feel comfortable answering that, but if anybody has any suggestions. I guess perhaps one of Mr. Milford's bottom line question is it an appropriate effort on the part of this Committee to answer that question and I certainly think that it would be something that this Committee could appropriately address whether or not we have the expertise or the experience in this Committee to make a policy recommendation to the Administrator who in turn would make I presume such recommendation to Congress.

But I certainly would welcome any discussion and be happy to recommend to the Committee that it take this on as a special issue.

DR. MOSES: Well this is only a personal opinion in terms of how I feel about this soft tissue sarcoma. First of all the evidence is from two studies in Sweden. It's very very suggestive, and I think it's obvious that it is not work going on in the United States. What needs to happen is for some other group to if they get the same, the other studies that are going on right now, if the same thing is found here and with the same -- -- in the neighborhood of five or six -- -- then if it's the same level, maybe two or above, I think this would be a little more convincing evidence to a lot of

people. It's very very difficult to document exposure fifteen or twenty years ago. When we do these kinds of studies we like to have enough of them done because of all those difficulties that they all tend to show. If there is consistency in the results, then I think people feel a little more comfortable saying that there really might be some type of a strong cause effect. But I agree with Dr. Shepard that I don't think cause and effect has been established -- -- and I think if enough studies we'll know more. When will the be completed? control study NCI study/ Isn't there a case being done by NCI? When is it going to be ready? I think that would be very helpful if that tends to show even if the risk is lower, if it tends to be in the same direction, I think that's very supportive if it's been found in Sweden. I don't know anything about compensation. Does Congress have to pass a law in order if it is found scientifically doesn't that require legislation for compensation? I don't really know.

DR. SHEPARD: I think it depends on the nature of it. Mr. Robinson from General Counsel Office is here. Does he care to express . . .

MR. ROBINSON: I don't believe that's so. I believe that's a determination that is made by the Department of Veterans Benefits and/or Board of Veterans Appeals as to whether it is sufficient evidence. It doesn't require additional legislation.

DR. SHEPARD: Did you write out, is it one ...

AUDIENCE: No sir, but it's directly related, and it's brief. My name is Mike Sutton and I'm with Vietnam Veterans Against The War. Regarding soft tissue sarcoma / and a point that you made that four hundred and thirty can be expected as a normal based on the American male population out of 2.4 million /Vietnam vets, I would like to ask the following: Are you going to take care in these studies that the general health of servicemen entering the service is higher than the average American male? Is this factor to be considered and allowed for in all the studies as a matter of fact? That the general health level of Americans male entering the service is higher than the average, and is there any way that this could be considered and allowed for in all studies, not only soft tissue sarcoma / but all studies being conducted?

DR. SHEPARD: I would say that that factor is taken into consideration when you have control groups of similar military background, but vary in their experience in Vietnam.

MR. SUTTON: Then the Ranch Hand control study would be very appropriate to this, but some others might have a cross section that would be not as solid, but the two veteran groups, those that were in Vietnam and those that were, or in the Ranch Hand and those that were not in

the Ranch Hand is one of the ways that you're going to allow for this by having people with comparable health at the beginning of the service.

DR. SHEPARD: Yes, as best as their ability, who should in the normal case of things have similar kinds of health requirements in order to get into the military.

MR. SUTTON : Thank you sir. I know you normally take questions from the audience later. Thank you.

DR. SHEPARD: I'm not sure we've answered your question Lew.

MR. MILFORD: That's okay.

DR. SHEPARD: Is it okay? Okay. I'm not sure there is an answer at the present time but it's certainly a question that has come up before and we'll continue to pursue it with interest.

A question: "How much money is to be spent by Mr. Moen's office on public relations regarding Agent Orange?"

I don't know. Do you have any idea of that? They have submitted a budget but I don't have their figures here, but I think it's safe to say that several thousand dollars are projected during the remainder of this fiscal year and in the out years. I don't have a figure. Okay.

"Why is there no state commission representation on this Advisory Committee?"

(DR. SHEPARD) I don't think that's been excluded. I'm not aware of anybody who has asked for that representation.

MR. WILSON: We've talked to Bart Kull about it and you know this is a topic brought up at least by New York and New Jersey on several occasions in writing and phone conversations. I thought this Mr. Kull would have reported our conversations in New York.

DR. SHEPARD: He's not a member of this Committee. If there are people who wish to have representation on the Committee I think an appropriate initial step is to communicate that fact to the Committee and it would be taken under advisement. The question of membership on this Committee has come up from time to time as one might expect and the principle under which we've been operating is that this is an advisory committee to the Administrator of the Veterans Affairs and to the Chief Medical Director and that it operates under a charter which is published in the Federal Register. If individuals either wish to resign from the Committee or wish to be considered for membership in the Committee, they should communicate directly with my office. We then will make appropriate recommendations to the Administrator. So I don't think there's been any, to my knowledge there's been no effort to exclude anybody from the Committee. I think there's some practical matters that in order for a committee to function

effectively it must have a relatively limited size. It couldn't be a huge committee and still conduct its affairs effectively. However, if there are individuals who wish to be on the Committee, I certainly would hope that they would contact me.

I've already answered I think the following question,

"Is there any method by which this situation can be changed?"

MR. WILSON: Excuse me. There's a question on the other side of that.

DR. SHEPARD: I'm sorry. "Suggest that all speakers provide summaries of their statements. Poor accoustics make it difficult to accurately take notes."

Sorry Wayne. We do, as you are probably aware, we do have a transcription of the Committee and those are available, so we ultimately will have a verbatim transcript of the Committee discussion.

MR. WILSON: It takes so long to get those transcripts out. The information from the hearing today is important for us to get out to our own people, so a summary, just a program would be very helpful.

DR. SHEPARD: Apparently our microphones are quite as effective as they might be. If anybody cannot hear, please put your hand up and make that fact known to us so that . . .

(HANDS RAISED IN REAR OF ROOM)

You're not hearing me now, is that correct?

AUDIENCE: Now we are.

DR. SHEPARD: I'll try and speak up and ask the members of the Committee to speak up. Is there anybody in the projection booth? Maybe we could turn up the sound a little bit. Thank you.

This question comes from Jack Stram, Minnesota Vietnam Veterans Against The War and Minnesota Veterans Coalition. Question No. 1: "The Agent Orange studies and protocols discussed all concern use in Vietnam of Agent Orange. What is the position of the Committee on the use of Agent Orange in the United States in or around military bases, and the use of Agent Orange on military bases overseas, and the storage and transport of Agent Orange by military personnel who have not served in Vietnam?"

Dr. Young, maybe you'd like to help us with this. Dr. Young is the expert on the use of herbicides, certainly by the military.

DR. YOUNG: We have been in fact compiling lists of individuals that were involved in various operations. For example Operation PACERIVY that was the operation that brought the herbicide back from Vietnam to Johnston Island and then Operation PACER HO was the operation that destroyed the herbicide in 1977. So all of those people do are listed we do have their

names on registries. We have a list of individuals who served at Eglin in the years when the program was involved in testing, so we have that group of individuals identified.

As to how to identify the individuals that would have been sprayed, say around the perimeter at Eglin Air Force Base in Northwest Florida, that would be very difficult to document although we know when many applications took place and we know the ground personnel in some cases who were involved in those military operations. We have not put together a registry at this time.

I would think that if studies that are ongoing come out positive, then a bigger effort will in fact be made to try to gather all that information.

AUDIENCE: This is just for you specific. Have you identified Operation -- (INAUDIBLE)

DR. SHEPARD: Please, when you're asking questions from the floor, step up to the microphone.

AUDIENCE: One of the operations involved was Operation Redhat on Okinawa in 1972 and we moved chemicals from Vietnam-- Agent Orange, Blue, White, Green, etc., and also World War II chemicals off the island. I personally was in Vietnam anyway, and I may have been exposed in the infantry, but a lot of the people that were involved in that operation had not been in Vietnam, including a lot of lower ranking privates who did a lot of heavy work. What I was concerned

about was whether or not the studies were going to take that kind of thing into effect.

DR. YOUNG: We don't have that particular Operation you listed. We do have the PACER HO, and if our records are complete in terms of where the herbicide was stored and shipped from . . .

AUDIENCE: A big "if".

DR. YOUNG: Yes, that's right, it's a big "if". I don't think we have an absolute record on where it all went. You may not be aware, maybe some of you are, but some of the phenoxy / herbicide, including 2,4,5-T / were in fact federally registered products. They are on a federal registry supply list and so many installations could have ordered the chemicals and got them and used them, and we don't even have today those distribution documents. So that's a tough problem and we've thought about it and we've tried to approach it by at least collecting names of individuals where we knew there were operations involving Agent Orange.

DR. SHEPARD: Thank you Dr. Young. Another question from Jack Stram . "Statistics published in 1973 showed a minority population of combat veterans of fifty percent or better over the duration of the Vietnam war. This suggests some kind of skewed percentage when compared to the percentage of minorities in the general population. Is the study weighted

for this skewing, and if most of the respondents are white, how does this affect the outcome or reliability of the study?"

I'm not familiar with that statistic. I guess it depends on how you define minority.

MR. STRAM: I was trying to figure a way to write that and it was hard to get it out. A man named Paul Starr in 1973,and in 1974 a man named Dean Philips did two studies on the statistics of minority and white populations among combat troops in Vietnam. What they showed was in combat units the average over the duration of the war approached fifty percent minority personnel in combat units as opposed to down to twenty and fifteen percent in the rear area units and units outside of Vietnam.

This suggested to me that if you do a study and do an outreach program and you get close to eighty percent or ninety percent white respondents which might be what the general population is, how does that affect the reliability or the outcome of the study, when in actuality the number of studies show that minority personnel had a much higher percentage of being in combat than did white personnel?

DR. SHEPARD: Okay. I guess my off the top of my head response to that would be that in any carefully controlled epidemiological study you would match on age, sex, race and any other determinants that you could identify so that you

identify so that you would not compare blacks with whites or vice versa, so that you would identify those groups and control for that difference.

MR. STRAM: You do control for it?

DR. SHEPARD: I'm assuming that's the case in any well designed epidemiology. That's a general position, and I can't give you specifics in terms of the Ranch Hand, but I think that's true, isn't it?

DR. YOUNG: Yes, in terms of the Ranch Hand study, indeed there were eight percent of the Ranch Handers were black and the control that matched them had to be too. So it was a one to one match based upon sex, age, race, service time in Vietnam, and position or responsibility in Vietnam jobs.

MR. STRAM: What you're saying is we can assume on extrapolation of that type of set up to the overall study.

DR. YOUNG: It would have to be done that way.

MR. STRAM: It will have to be done. Okay.

DR. YOUNG: But your interesting figure here. I have an article called Who Served in Southeast Asia, Who Saw Combat? by Richard Hammond. That particular article does say forty-seven percent black, but it's a qualifier of those individuals who were interviewed, a hundred ninety blacks were interviewed and of that eighty nine said that they had served in Vietnam. They interviewed two thousand

two hundred twenty nine whites and they said that forty-one percent had served in Vietnam. So the figure forty-seven percent here doesn't say that that's what composed the actual combat unit, but rather of the blacks interviewed that said they'd served in Vietnam. So there's a discrepancy in the figures.

MR. STRAM: The one Paul Starr did was a Department of Defense statistics breakdown. It's called The Discarded Army Veterans After Vietnam. It's all statistics and it's hard to read. It was published in 1973, but that's where I got that. Thank you for your patience with those two questions.

DR. SHEPARD: Thank you. Another question.

"Because of the use of Agent Orange for many years and current use on national forests, power line access and highway shoulders leading to contamination of underground aquifers and water supplies, how will this affect your study, control groups, and quality control."

This is from Steve Wessing of WZRD Radio, National Federation of Community Broadcasters. My response to that would be that we are concerned about non-military exposure to herbicides and I think that in the design and administration of questionnaires, the question of non-military exposure to herbicides is usually included or has been included in some studies anyway, so that

to the extent that we can solicit or elicit that information, we will. Now obviously if waters are contaminated and the individual drinking that water isn't aware of that contamination, that is not going to come out in the questionnaire

So I'm sure there are going to be some gray areas in this area, but hopefully if you study large enough populations, and you don't concentrate your populations geographically, then I would think that those issues would dilute out, but I would defer to an epidemiologist on that.

DR. HODDER: That consideration is much more important in a case control study where you starting with people with a disease who may have had it caused by either exposure in Vietnam or exposure on a farm. In this particular situation you are identifying people who are either exposed or not exposed by a location in Vietnam and what your assumption would be is that these people's risk of being exposed in the States should be roughly comparable. You have no reasons to suspect otherwise that your control group is different. Therefore, this way you're relying simply on a random process that your control group and your exposed group were the same.

DR. SHEPARD: Any other comments from the members of the Committee? Okay. "In regards to the epidemiological study, what efforts have been made to contact the government of Vietnam and either study

their data or send a fact finding team over?

If no effort has been made, why not?"

Participant: Who asked that?

DR. SHEPARD: It doesn't say. It's unsigned.

MR. HUBNER: Leonard Hubner, Minneapolis, Minnesota.

DR. SHEPARD: Okay, fine. Thanks Leonard. In the matter of the VA soliciting information or data in Vietnam, the VA has not. There are a number of reasons for this, some of which relate to the fact that the VA is a federal agency. We do not have diplomatic relations with Vietnam. The VA would find it difficult to sponsor a group of scientists going to Vietnam, As you probably are aware, there has been a suggestion that a group of non-government scientists go to Vietnam, and I think it's also accurate to say that that has happened. Other than the National Academy of Science's report which I think was published in 1974 which looked at some of the environmental ecological effects of these herbicides in Vietnam and does not say very much about the human health effects, I'm not aware of any sound U.S. or international scientific body which has made such an assessment in Vietnam. Now that isn't to say that there wouldn't be some merit in having such a scientific group of international reputation conduct some studies.

Where I come out on that question is that I would find it very difficult to make a relationship between what one

would find in Vietnam today and what our troops experienced in Vietnam. I think it would be a much more difficult to make that link than if we were to study the individuals who we know were in Vietnam and we have some sense as to who was exposed and who wasn't. So although it might be a fruitful scientific venture to do that for the sake of determining the status of the health of Vietnamese, I have difficulty making that connection, making any connection of that information and how it would affect our decisions here, I would really like some opinion from the rest of the Committee on that point.

The science panel has addressed this issue on a couple of occasions, that is the science panel of the Agent Orange Working Group, That's been essentially the consensus opinion, but if there are others who feel differently, I'd like to hear them. Dr. Murphy?

DR. MURPHY: There aren't any other groups that have explored the published allegations from North Vietnamese scientists regarding this? Has this come before your science panel or Working Group?

DR. SHEPARD: This Committee did in fact evaluate some reports coming from Dr. Tung in Vietnam, and that is a matter of record of this Committee. Similar analysis have been made by other groups such as the science panel, Dr. Walter Rogan, I think, was the one who composed this Committee's

opinion and certainly as I say the science panel of the Agent Orange working group has discussed Dr. Tung's work. I think the consensus of this is that the statistical base from which he drew his conclusions was not entirely consistent with the quality of statistics that we would regard as establishing conclusions.

Any other members of the Committee care to comment on that? "U. S. service personnel were given a clean bill of health by the U.S. Government prior to their departure to Vietnam. Ten years later these men are sick and dying. Isn't this proof enough that something in Vietnam led to their health determinations? It is obvious that these conditions were created in Vietnam. Vets need treatment and compensation immediately, not after a twenty year study."

I'm trying to get the question out of this. Your comments I certainly hear and appreciate. Isn't this proof enough that something in Vietnam led to their health deterioration? I think that until we get more information from epidemiologic studies, and it'll be long before twenty years, hopefully, that question should be answered. I personally feel that we don't have a scientifically valid answer to that allegation that people are sick and dying in larger numbers among Vietnam veterans than non-Vietnam veterans. I know that many of them

have problems and we certainly are aware of that and are addressing that. Public Law 97-72 authorized the VA to provide health care under certain guidelines that have been promulgated so that treatment is being provided. The issue or question as to whether or not there is a higher incidence of illnesses among Vietnam veterans who actually served in Vietnam than in their non-Vietnam service counterparts I think is still an open question.

Any other members of the Committee wish to comment on that?

AUDIENCE: You know I realize that after the study or during the study you say that we don't have significant, enough proof that there are veterans who are sick and dying. One thing is that we have to consider is that when we enlisted to go to Vietnam or when we were drafted, we were all given medical examinations. These medical examinations said these are America's finest men. We went to the war, and now we come home ten years later and we see hundreds of men with these various forms of carcinoma that are just popping up in our age group that we don't see in previous age groups. Now whether it was something with our environment here as we grew up when we were younger before we went to Vietnam is probably a question that could never be answered, but when we look at some of the dermatological types of manifestations that we see on the vets who have

returned, when we look at the Vietnamese people some of the evidence that Dr. Tung has brought home here, or brought back to our country, and just correspondence that we have personally with veterans, we see that there was something there, whatever that something is.

We don't see men coming home and ten years later a bullet hole manifests itself and that is something that can be compensated for, or ten years later all of a sudden a man's leg falls off and that's something that he can be compensated for.

What we're seeing here I think is a pathology that is completely new to veterans, that is veterans from World War I or from the Civil War or whenever we started compensating veterans for their war injuries, and we believe indeed that Agent Orange, the manifestations we see from it, is a viable disability, one that should be compensated for.

And one thing, speaking as a veteran, is we see so many of our brothers that are at home that could not make it here because of these illnesses and when they go to the VA and they come back home they receive very few answers and very few answers in consideration of what's going to happen to their children.

So this is what I mean as far as that there are indicators there that are saying that something has happened to these men and as far as like a proof, the cause and effect

relationship, I don't think that you're going to see it right away and maybe even after a ten year study if you're going to see it right away. That was why I questioned the idea of going to Vietnam or sending an independent fact finding mission or an international mission to look at the pathologies that are being seen there and to compare them with those there and to give the vet the shake that he needs.

I mean after all we did go over there for the country. Thank you.

DR. SHEPARD: Well, I certainly sympathize with the problem. We are doing things I think that address the issue of treatment and certainly we want to get to the bottom of this question.

Okay. This is unsigned but I'll read it. "Could you comment on the ability of VA to act on the veterans behalf to push the Agent Orange program forward?"

I think that what you've heard today, I hope, will give you some idea that the VA is pushing its program forward.

"The bias attitude of VA may hinder -- date of treatment. Will the VA be the ultimate source of treatment?"

Well, I guess that I can only speak for the VA and its source of treatment. I'm not sure that this is what the question was addressing, but in the event the VA detects a need for

treatment and does not have that capability within its walls that certainly opportunities and authority exists for fee basis treatment outside the VA. I'm not sure that's the question being raised, but that's what comes to mind.

"Would it not be better for an outside source to treat affected veterans?"

I think that's a judgment call. I think the VA has a very good health care delivery system. I'm not in a position to compare it to any other large health care system and I'm not aware of any areas in which the VA is not giving good care for health related problems.

"Can a program be initiated to get all veterans tested?"

In that regard no veteran is excluded from being tested in the Agent Orange registry process. So any veteran who is worried about a health problem that may have arisen from service in Vietnam certainly is eligible for testing, examination and the results of those examinations are shared with the individual.

"You speak about a skin disorder. Do not know if it is Agent Orange. I don't think vets are being encouraged. Four hundred out of 2.4 million veterans affected seems like a small number."

I presume that that refers to me statistic on soft tissue sarcoma/ All that is is an estimate based on nationally published

rates, so that's just an extrapolation of some 1.5 per hundred thousand extrapolated out to 2.4 million.

"I see lots of work to study but what about treatment now?"

Treatment is being provided now under the law. It was provided but now that provision authority is more specific in terms of 97-2, so I think it's accurate to say that the VA is providing treatment.

Yes, is this your question?

AUDIENCE: No, it isn't.

DR. SHEPARD: Okay, can I just get through the ones I have here?

AUDIENCE: Certainly.

DR. SHEPARD: This is from Ron Kruger. "What information gleaned from the literature utilized in the formulation of any of the VA epidemiology studies or any other VA activities that are planned or are presently under way?"

Okay. The literature analysis, which by the way I think was a very useful effort, and we commend the Congress for having mandated its being done, has provided a very useful resource to VA researchers. In fact, many of the solicitations, excuse me, many of the proposals that have come in as a result of the solicitation are direct reflection of some recommendations that have flowed from that literature

analysis. That literature analysis has point out areas where additional research could fruitfully be done and I think that that has triggered the response to the solicitation.

In terms of any other VA activities that are planned or presently under way, I think that it's safe to say that the literature analysis has had at least an indirect / if not a direct effect on many of our activities. It's certainly a very valuable document and we've made I hope good use of it. Does that answer your question? Did you have something more specific in mind?

AUDIENCE: You said the request coming in in response to your solicitation / what exactly are you talking about?

DR. SHEPARD: The VA sent out a solicitation for proposals for research related to Agent Orange. It is my impression that the nature of those proposals has been in part at least the result of scientists looking at the literature analysis and picking up on areas in which / there is inadequate research or questions which have not been adequately answered by research efforts.

AUDIENCE: This is separate from the epidemiology studies?

DR. SHEPARD: Yes. Solicited proposals are quite separate from the epidemiological / studies. Here's one from Todd Ensign.

"As you know, Vietnamese doctor and researcher Dr. Ton That Tung / died last Friday . . ."

No, I didn't.

MR. ENSIGN: Yes, heart attack.

DR. SHEPARD: I'm sorry to hear that. Dr. Tung / was in this room as you may know about two-and-a-half years ago.

"This may be an appropriate time to reconsider efforts at scientific cooperation with Vietnam particularly in the area of TCDD effects. Is any such cooperation currently being considered by the VA and for this panel?"

I think I may have answered that question by a previous one but we can reopen it if anybody has any other ideas.

Another question from Todd. "Citizen soldier study conducted by Dr. James Dwyer of four thousand one hundred fifty three Vietnam vets identified seven cases of soft tissue sarcoma / This is clearly in excess of your 1.5 per hundred thousand. What specific plans does the VA epidemiology study have for dealing with this issue?"

I sense Todd that you're comparing the incidence in that four thousand with the general population incidence and I'm again not being a statistician or an epidemiologist, but I have some concern about making that comparison. I doubt that some four thousand is a randomly selected group of individuals so that it may well be that there it would represent perhaps a larger number of individuals with health

problems than the general population. Specific plans that the VA epidemiologists have for dealing with this issue certainly we include looking for all health outcomes and with all the attention focused on soft tissue sarcoma. We'll be particularly interested in seeing the incidence or occurrence of soft tissue sarcoma in the study subjects. Any comments?

Those are all the written questions I have. Does anybody have any other questions, questions from the floor? If you would be kind enough to identify yourself so the recorder can ...

MR. HOLT: I'm Reed Holt. I'm with Vietnam Vets Against The War. I came up from South Texas and I'm a carpenter for work right now but I do anything, I know out of common sense that in order to build a roof on a house, for example we got to have four walls to hold it up. Now a little while ago and repeatedly throughout the published minutes of the Committee meetings here taking place over the last couple of years and also various statements made by a lot of people on this Committee throughout the years whatever their capacity was at that particular time, have told me that I have the ability to build a roof and set it up without building a house. One example is when we're talking about identifying exposure, meaning we're going to have to correlate that veteran's area of operation at a time when this Agent was used and be able to draw from that to what degree was he

exposed and then work from there, soft tissue analysis, sarcomaany other sort of testing is being presumptive because you do not have an exposure index. No one here has worked on an exposure index, and I think one has to be established before we go on to guess what levels are going to qualify that veteran for treatment, what levels are going to qualify him for being sick. No one on this panel right now, that I'm aware of, knows of the available information that's excluded in your bibliography that include areas of wind drift, except for perhaps Major Young. Volatilization at so many degrees Farenheit that turns the dioxin content into a vapor which could blow anywhere in Vietnam, or surface water run off metabolizing animal or plant systems.

No one knows of these routes of exposure. What we're trying to do is limit those who can account for heavy exposures at certain times and have them or the government back that up with massive documentation. First, prove that he was exposed, one. Secondly, go on to find out if we can give him a test, does he have symptoms. That's excluding a large large number of Vietnam vets, not to mention domestic exposure victims. Secondly, we're putting the roof on the house before we build the walls if we go any farther from that point. We're being presumptive here and I recognize the fact that the VA is going forward with this issue, but I also recognize the fact that we may have taken an exit somewhere

back and we're headed off in the wrong direction.

DR. SHEPARD: If I may just synthesize your question. Are you concerned about the methodology of establishing an exposure index?

MR. HOLT: I'm concerned about the establishment of an exposure index period and the evaluation of all available data whether it be Swedish, Canadian, American and perhaps Vietnamese if any is available, on areas of exposure that properties of dioxin and any other compounds.

That's been disregarded here because we're working on presumptions based mainly coming out of the chemical industry from what I can see here. Going over the preponderance of abstracts and available data I have yet to come under an evaluation based on all the data, including exposure, routes of exposure, volatilization, wind drift, adherence to particulate. That's not included and that's a main factor and a personal chip on my shoulder.

You could study for twenty years and if you don't include this in your assessment, and right now you've gone awfully far and it doesn't look like you have, I don't think we're going to come up with, or better yet I don't think you're going to come up with any answers. And I see myself in twenty years being in the same position.

I've carried briefcases and wore three piece suits and now I'm walking in the streets because as an American I know

that's the most effective route I have to try to redress my grievances. It's worked before and I'd just like to see the Committee open up and not be, in my prejudicial view, that's biased in their acceptance of information/available.

The Swedish study is good. We can compare it with an American study, sure, fine and good, but we can't discount it. We can't say that just because it's a positive, it's a negative because we have nothing to match it with. That's not scientific at all. I'm a carpenter and I have a basic foundation of knowledge here to know what information is acceptable and what isn't.

DR. MOSES: Okay, let's say the Swedish study are two walls. I'd like to give you the other two. Okay?

MR. HOLT: Okay. That's all that I've got to say and I've got to go back out in the streets.

MR. WESSING: I'm with WZRG in the National Federation of Community Broadcasters. I'd just like to ask how many million tons of Agent Orange was dropped? And isn't it true it was used to make US1 and it was used to make all the roads in Vietnam?

DR. SHEPARD: I forget. Our expert here on Agent Orange -- I forget the number of millions of pounds of Agent Orange.

DR. YOUNG: We're talking about eleven million gallons and at ten pounds per gallon you can work that out,

but it wasn't used to make the roads. Quite the contrary. The roads were put in many years before in most cases, in many cases in Vietnam, and the herbicide was used to defoliate along side the roadways rather than to make a road.

But about eight percent of Vietnam was sprayed with herbicide and a good many servicemen would have been exposed as a consequence.

DR. SHEPARD: Unless there is some other pressing questions, I think we'd better adjourn the meeting because we have to reconvene . . . yes?

MR. MILFORD: I have a question.

DR. SHEPARD: One more question.

MR. MILFORD: This is a question about the secrecy that was alluded to before about the disclosure of portions of the protocol. This is a question about the secrecy about which the portions of the protocol has been shrouded in the last five or six months, and the question, also the issue of having non-governmental scientists review that, particularly outside of governmental context. The thing I would like to ask is: is the Committee to reconsider the notion of holding a closed meeting concerning the portions of this protocol? As you said, the split on this is perhaps 60-40, take your division as you like. If the question of the Agency's credibility is at stake, which it has been for several years, I would ask this Committee to consider whether that whatever

credibility remains may be completely compromised if the portions of the protocol remain in secrecy as they have. I raise that particularly in light of the comments that were made by one scientist with the White House work group panel, the copies of which I've obtained. One of the six reviewers said in fact that the questionnaire and portions of the protocol were so bad that it should not continue forward.

I did not see the identify of the scientist. That was not disclosed, but one of the reviewers for the White House work group panel had some very critical comments to make about the questionnaire and the remaining portions of the protocol. If that's the case, I think there may be more dispute about this than seems apparent so far.

The second question is about National Academy of Sciences. Will the VA be bound by any recommendation made by the National Academy of Sciences if that recommendation goes to the question of the Agency conducting the study? As you know the National Academy of Sciences reviewed the Ranch Hand protocol, recommend that the Air Force not conduct that study. The Air Force ignored that recommendation and went forward and conducted the study.

DR. SHEPARD: Okay. That wasn't quite the way it happened. They didn't recommend, they raised the question the credibility and the issue was brought before the Science Panel of the Agent Orange Working Group. The Agent Orange

working Group made its recommendation that the Air Force be directed to proceed and that ultimately did happen.

In the matter of the National Academy, first of all I think we alluded to earlier, it'll be a different committee of the National Academy of Sciences that reviews our protocol, not especially by design but we just thought it would be appropriate for an epidemiological board to review an epidemiological protocol, or an epidemiological committee to review an epidemiological protocol.

When you say is the VA going to be bound by the decision or recommendation of the National Academy of Sciences, I don't know of anything that would cause the VA to necessarily be bound. Obviously it would be foolish if the VA did not take into close consideration the recommendations and views of such a prestigious organization as the National Academy of Sciences.

It might also be pointed out that the National Academy of Sciences gave very high marks to the majority of the Ranch Hand protocol. It was a question of the credibility and the size of the cohort that was questioned, that was reviewed by a number of other equally prestigious groups and the consensus ultimately came out the way I've indicated.

Any other questions?

MR. MILFORD: The closed meeting. There is a closed meeting?

DR. SHEPARD: Yes, there is a closed meeting. We'll convene at one o'clock.

MR. MILFORD: I know there is a closed meeting. The question was whether the Committee would reconsider that notion in light of some of the comments that have been made, and I thought it very important that the others members of the Committee realize that, there's not unanimity about the quality of that protocol as it exists in its second round, that there's some serious criticism by the White House work group panel of that protocol and in particular the question of whether it should be disclosed. I think it's extremely important that that issue remain and be considered by this Committee if it's to be in effect a committee. I think it has to make some recommendations as to those kind of quality questions.

DR. SHEPARD: Dr. Hodder?

DR. HODDER: Well, it seems there's two questions that you're raising. We can't very well say anything about the questions themselves. We can't agree or not agree unless we see those, the questionnaire.

I'd like to clarify also and make sure I have it right, the closed meeting this afternoon is closed to the people who are potentially subjects so that we may not introduce a problem. It's not closed to their representatives as I understand it. Is it?

DR. SHEPARD: The meeting is closed to everybody who is not a member of this Committee.

DR. HODDER: That's right, but Mr. Moen, he's invited?

DR. SHEPARD: Yes, yes.

AUDIENCE: If the Advisory Committee is to be, the credibility is to be impaired by that -- -- -- beyond the VA, it would go to everyone who is represented on this. I think the protection of the veteran is important. You have four members of veterans organizations here. So I don't understand why that closed meeting would impair the VA's credibility.

DR. SPENCER: Well the point is that in the past many of the materials prepared by the VA have only been subject to intensive scrutiny once they've been released to the public and other scientists had an opportunity to review those. In particular the initial protocol came under some serious scrutiny only after there was a fairly full disclosure of that. A particular scientist that we submitted that material to drafted something like a twenty page document that reviewed that fairly intensely. Most of the recommendations from scientists we had look at that were followed and agreed to by many members of Science panel, and I think it behooves the government to gain some credibility on these questions by having full disclosure particularly if, and the

other point about this is the bias that's been suggested to result from this. I think there's a significant controversy about whether any bias in fact will result and if it does whether there's sufficient verification procedures in the standard epidemiological methods to eliminate any bias that might result, I think you've got to make a call about the credibility versus the bias, and you've got some problems in that area and I would suggest that you opt for full participation and openness rather than secrecy.

AUDIENCE: May I get this straight? You're mentioning the fact that the first report of that science advisory panel panned the protocol. Is that correct?

DR, SPENCER: The first panel did on the second submitted protocol.

AUDIENCE: Is that the same protocol that we are now supposed to be looking at?

DR. SPENCER: That's right.

DR. SHEPARD: No, that's not correct. We're looking at the third submission.

AUDIENCE: Oh, okay.

DR. SPENCER: Then I don't think the statements made are necessarily correct here until we see what we have to look at. We may pan the same thing. I think it was pretty well panned the second time, the second one that came to us too.

DR. SHEPARD: The first was.

MR. FURST: The first one that came through. I have not seen either one of them.

DR. SHEPARD: I think it's also accurate to say that there's not been public disclosure of the entire protocol by the entire group so that this is not in deviance with what has gone on by other reviewing groups.

Okay. Thank you very much everybody for your kind attention. We'll reconvene the Committee at one o'clock.

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A U T H E N T I C A T I O N

This is to certify that the attached proceedings before the Veterans Administration, in the matter of: Advisory Committee of Health-related effects of herbicides, Date: May 13, 1982, Docket Number: _____, Place: Veterans Administration Central Office, Room 119 810 Vermont Ave., N. W., Washington, D. C. was held as herein appears, and that this is the original transcript thereof for the files of the Administration.

Carol Mock
Barbara J. Becker
Free State Reporting, Inc.

I hereby certify that the proceedings and evidence herein are contained fully and accurately, as corrected.

BARCLAY M. SHEPARD, M.D
Chairman, Advisory Committee on Health-Related Effects of Herbicides

September 8, 1982

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

(THIRTEENTH MEETING
AUGUST 31, 1982)

January 1983

Washington DC 20420

VETERANS ADMINISTRATION

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ADVISORY COMMITTEE ON HEALTH-RELATED
EFFECTS OF HERBICIDES

- - -

Veterans Administration
Central Office
Room 119
810 Vermont Avenue, N. W.
Washington, D. C. 20420

August 31, 1982

The Committee met, pursuant to notice, at 8:30 o'clock, a.m., BARCLAY M. SHEPARD, M.D., Chairman presiding.

MEMBERS PRESENT:

BARCLAY M. SHEPARD, M.D., Chairman
Special Assistant to the Chief Medical Director
Veterans Administration Central Office
Washington, D.C. 20420

MAURICE LeVOIS, Vice Chairman
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THEODORE P. SYPKO
Field Representative
Veterans of Foreign Wars
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200 Maryland Avenue, N.E.
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ALTERNATES PRESENT:

(For IRVING B. BRICK, M.D.)
THOMAS J. FITZGERALD, M.D.
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National Veterans Affairs
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The American Legion
1608 K Street, N.W.
Washington, D.C. 20006

(For JON R. FURST)
HUGH WALKUP
(National Veterans Task Force
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Seattle, WA 98104

(For PHILIP C. KEARNEY, Ph.D.)
ALFRED RIVAS
Office of General Counsel
Department of Agriculture
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South Agriculture Building
Washington, D.C. 20250

(For CHARLES A. THOMPSON)
DAVID W. GORMAN
Administrative Assistant
National Service and Legislative Headquarters
Disabled American Veterans
807 Maine Avenue, S.W.
Washington, D.C. 20024

I N D E X

P R O C E E D I N G S

(8:30 a.m.)

CALL TO ORDER AND OPENING REMARKS

DR. BARCLAY SHEPARD: Good morning ladies and gentlemen. I think we best get started. We have a fairly full agenda, as usual. And, I'd like to welcome you all to the quarterly meeting of the VA Advisory Committee on Health-Related Effects of Herbicides.

We welcome your presence and are delighted to see so many familiar faces and a number of new faces. And, I hope this will be an interesting morning.

We're delighted to have a number of visitors, particularly representatives from the state of Illinois. Senator Berning and his group will be addressing us later on in the morning. And, we're also delighted to have some new members of the Committee. And, I would like to welcome Mr. Hugh Walkup, who is with us for the first time, representing the National Veterans Task Force on Agent Orange.

Jon Furst, who is the designated member from that organization, was not able to be with us. And, Hugh has been kindly consented to fill in for him as his alternate.

As you know, we have provided time in the agenda for questions to the Committee, and, we encourage you to

prepare these questions. Don Rosenblum, our very able Executive Assistant, will provide you with cards and pencils, so that if you would please prepare your questions and direct them to the Chair at the appropriate time in the agenda.

We have had some recent changes in membership. Dr. Albert Kolbye of the Food and Drug Administration has retired from public service. And, we have Dr. Frank Cordle who is representing that Department.

We are also pleased to have with us, of course, Mr. Maurice LeVois, who will now be acting in the official capacity as Vice Chairman of the Advisory Committee, subsequent to the action that was taken at our previous meeting, and his appointment to that capacity by the Chief Medical Director.

We will be particularly pleased, a little later on in the program, to welcome our just recently sworn in Deputy Administrator, Mr. Everett Alvarez, who will be addressing the Committee and members of the audience. And, also, we're delighted to have today Mr. Derek Volker, who is the Secretary of Veterans Affairs for the Government of Australia. He will be visiting -- he is visiting Washington with his family and has been kind enough to take some time out to be with us this morning. So, they will be appearing a little later on.

A number of activities have been in progress since our last meeting; and, we want to just bring you up to date on some of those. As some of you are aware, the Administrator has approved a funding package for the conduct of a number of studies and other Agent Orange related activities.

And, I just would like to run down those efforts. Some of them are not new. Some of them have been on-going. Some of them are relatively new.

First of all, for a long time we have recognized the need for a Research Projects Office, to be headed up by an experienced research epidemiologist with appropriate staff support. We have been working hard to put together the positions and the position descriptions for this office. And, we now have the approval from the Administrator for the establishment of such an office.

We are now recruiting actively to fill these newly established positions. We're hoping that in that process we will be able to attract individuals with national reputations to help us further our research efforts, as they relate to Agent Orange.

About the epidemiological study, I'll have a little more details, as I say, later; but, we have now

been approved for funding of a pilot to kick off the full scale epidemiological study.

As you know, we've been working towards developing a mortality study of Vietnam veterans, in which we'll compare causes of death and death rates, comparing those for the Vietnam veterans and the Vietnam era veterans who did not serve in Vietnam. I'm happy to report that funding for that effort has been approved; and, we are negotiating a contract with the National Academy of Sciences to do a part of that, and two other contracts.-- The requests for proposals have been published in the Commerce Business Daily. And, we are awaiting proposals for such things as the identification of Vietnam veterans who actively served in Vietnam, verification of service in Vietnam, and also a coding process for causes of death as they are reflected in death certificates. So, we're pleased to see that the mortality study is moving along.

The Agent Orange Registry continues a pace. We're now up to close to 95,000 veterans who have been examined in our registry. And, we are moving ahead with the plans for revising the coding process in order to make that information more readily available and a more useful mode.

The matter of the chlorance problem has got a recent shot in the arm, in that we have restructured the

chloracne task force and have now a new Chairman in the person of Dr. Betty Fischmann who is the Chief of Dermatology at the VA Medical Center here in Washington.

We have provided her with additional staff support; and, I'm looking forward to moving out on that still complex issue.

We have identified, through a process of claims reviews, some 10 to 15 individuals who might conceivably have chloracne, based on the fact that they have a skin eruption that is of the acniform-type. We're now in the process of contacting some clinics around the country; and, we'll be setting up special examinations -- or offering special examinations to these veterans if they wish to participate in that process.

We have in the wings a very exciting study which will be conducted by the St. Louis VA Medical Center. It's a study of identical twins. We hope to identify approximately four or five hundred pairs of identical twins, one of whom served in Vietnam and one of whom -- the other of whom did not, but was in the military.

This will give us the capability of measuring some of these more subtle conditions of which veterans have raised concerns; a matter of some of the more subjective symptoms, such as some of the neurologic and

emotional disturbances that have been alluded to. The funding for that study has been approved.

Some while ago, you may recall that our Department of Research and Development issued a solicitation for Agent Orange related project - studies. That has resulted in submission of a number of projects, and those projects have undergone a merit review process.

Ten of them have been selected for funding. The fundings for those ten has been approved.

So, we have ten research projects in the middle, which are moving forward at our various medical centers around the country. These are investigator initiated research projects, relating to such issues as toxicity and animal models, physiologic measurements, and so forth.

We are hoping to fund an update of our Agent Orange literature review. The review, accomplished by contract, is a two-volume work. The review included articles available of October of last year. So, almost a year has gone by; and, there are a number of new articles in the literature. And, we will, therefore, update the existing report. And, we look forward to that effort soon.

Dr. Alvin Young will be speaking to you later on in the program about some of the details of a monograph

series. We hope to produce a series of monographs on various aspects of health problems of Agent Orange and other issues. And, approval has been granted for the funding of that monograph series. So, we are looking forward to that effort.

One other thing has been of particular interest to me is the matter of our patient treatment file, which is a very rich research potential; that is, any veteran that's being discharged from a VA hospital is entered into a automated patient treatment file. And, that contains such important information as demographic information, age, sex, race, home address, and that kind of information; but, also, gives details of the diagnosis, illness, period of service and so forth.

One thing that has not been a part of that effort has been theater of service. In other words, we don't know, from looking at the PTF whether an individual has actually served in Vietnam.

So, another effort, which has been approved for funding, is a contract for a retrospective analysis of the -- of a sample of Vietnam era veterans, who are in the patient treatment file, in order to establish or to distinguish those who actually served in Vietnam from those who did not. So, that will be a retrospective effort done by contract.

Prospectively, I'm happy to announce that as of the first of July, we have in place a system that will distinguish any Vietnam era veteran coming into a VA hospital, either for in-patient care or out-patient care, as to whether or not he served in Vietnam.

The patient data card will identify those Vietnam era veterans who actually served in Vietnam.

For the first time we'll be able to distinguish those veterans who actually served in Vietnam from their peer group who did not serve. This will give us, I think, a handle on and an ability to start looking at some of our own internal VA data systems and make some comparisons between those two groups.

And, last, among the research projects and efforts that I'm alluding to is another very exciting study which will -- which we hope will develop. It's still in its exploratory phases. But, we hope to cooperate with the Environmental Protection Agency and the Department of Agriculture and the Department of Health and Human Services in funding an interagency study to analyze dioxins in human fat.

The Environmental Protection Agency for the past several years has been collecting adipose tissue samples

from individuals who have undergone autopsy following unexpected death, such as automobile accidents and so forth, in order to distinguish them from individuals who have died as a result of chronic diseases.

They have an adipose tissue bank, as I understand it, of some 12,000 specimens. The EPA has a contract under way for an inventory of those specimens and for identifying the individual from whom these specimens were taken, as regards age, sex, race, and military status.

We believe that there will be in that sample of 12,000,or in that group of 12,000, a sample of Vietnam era veterans and possibly veterans who actually served in Vietnam.

Our contribution to that study has been approved by the Administrator.

Hopefully, we will be able to make some assumptions as to the presence of dioxin and, perhaps, its significance. So, we're hoping -- looking forward to that effort.

In addition, we've been approved for a continued and, perhaps, more vigorous information outreach program, to be headed up by our Department of Public and Consumer Affairs.

Well, that gives you kind of an overview of what we've been involved in since our last meeting. As I say, not all of these initiatives are new. Some of them are. But, I just wanted to give you a little update.

In the matter of the epidemiological study, I wish I could inform you that the study was under way. The long awaited study is still not under way; but, we are, I think, creeping towards that end.

Another step -- an important step -- that has taken place since our last meeting is the fact that the National Academy of Sciences is now reviewing the protocol submitted to us by UCLA. We expect their report in the next three weeks. And, I hope that that will give us more answers to such questions as: Two or three cohort approach; that is, two cohorts in Vietnam, one cohort who did not serve in Vietnam; and perhaps even more puzzling and more difficult of the whole issues -- exposure, levels of exposure, appropriate sampling of the cohorts, the actual construction of the cohorts, and such issues as that.

So, we are looking forward to their reports shortly. And, we're also looking forward to being able to

award a contract for the pilot study. The present plan calls for a pilot study of some three hundred veterans in each of the cohorts to be studied. We're trying to do that by contract; and, as I say, funding for that contract has been approved by the Administrator; and, we're now in the final phases of putting the RFP together. We hope we will be able to encourage investigators of national reputation to respond to the RFP.

That's about all I have to say at the moment. I'd like to turn now to Maurice and ask him if he would give us an update on some of his activities.

REPORT BY THE DIRECTOR, AGENT ORANGE RESEARCH

MR. MAURICE LeVOIS: Thank you, Dr. Shepard. I'll keep my remarks brief. We'll be receiving a visit by Derek Volker and the new Deputy Administrator soon.

I'd like to welcome everyone in this rather large crowd today. It's a pleasure to have you all here. And, I think that this large turnout demonstrates the importance of this Agent Orange issue and continued interest and even a growing interest on the part of the public.

Six months ago my office was created. It was established to assure a prompt and comprehensive response to this issue by the VA. And, as Dr. Shepard has just summarized, I think that some progress has been made in that respect. The VA has planned an ambitious and well

balanced research program. And, a large budget has been approved by the Administrator to help us in that regard.

We're presently recruiting top scientists -- hope to get an especially highly qualified epidemiologists, as an overall, scientific manager in this area. And, the VA has started an information outreach program. It has managed to follow up on the addresses of the people who have taken part in the Agent Orange Registry, the first of a planned series of mailings to register them, identifying them as, among our constituents, the most concerned individuals, at least those who've expressed their concern.

And, I think a great deal of effort has been expended by the VA with consultants, and a subcommittee of the Agent Orange working group, along with members of the Army Agent Orange Task Force, in resolving a very critical problem of selecting the correct study subjects for the epidemiology research that's been mandated by Congress.

Today, we'll have an opportunity to hear the comments of our advisory committee members on our studies; and, also later, to address comments and questions from the floor.

The VA benefits from this forum, from the wealth of ideas and the information that is shared here.

I think that this group is helpful in keeping the VA headed in the right direction. I feel that we are headed in the right direction right now, but the challenge, as alluded to by Dr. Shepard, is to make rapid progress now.

We have taken some important steps; and, at the moment, we need to proceed posthaste and get the studies under way, and get some results, to make the basic decisions, and also to put information before the veterans.

Right now, Dr. Shepard, you might want to comment in more detail on the center piece of that research program, which is the major epidemiology study, and the work that we're involved in in that epi study, and the pilot phase of that study, in particular.

EPIDEMIOLOGICAL STUDY

DR. SHEPARD: Thank you, Maurice. One of the problems -- and the members of the Committee, I think, have been very diligent in pointing this out to us -- has been the matter of identifying the cohorts in a way that will be both accessible to the veteran community and to the scientific community.

I'd just like to say again how much we have appreciated the efforts of the Chris Young and his staff. I think he's with us today, I'm happy to see. They have

really worked very, very hard at a very difficult, complex task of sorting out the military records and trying to get as much information as is possible, and information which has a direct bearing on the whole process of cohort selection.

As I'm sure you're aware, this matter of the records dealing with operations in Vietnam and records reflecting who actually served, in what capacities, and at what times has never been an automated set of records. A hand search of records has been required in order to shed the light on this perplexing problem.

And, you can imagine the magnitude of several years, several million people serving in various capacities. That is a mammoth task.

As a result of the fact that these records are not automated and one delves further into the records, new information is bound to come to light. As that information comes to light, it has, from time to time, colored the whole process of how we select the cohorts.

So, it's been a -- it's been a dynamic evolution. And, we are still in that evolutionary mode. We do not have a fully agreed upon, very specific, step-by-step method by which these cohorts will be selected. That may sound as though we should have be further along than we

are. But, as I say, this -- this whole process has been one of evolving issue. And, therefore, we have to adjust to situations as they arise.

In order to arrive at some consensus or to direct efforts along that goal, Dr. Vernon Houk, Chairman of the Science Panel of the Agent Orange Working Group has appointed a subcommittee to, in fact, do just that -- to develop a cohort selection protocol, one that can be reviewed and can be agreed upon by various elements involved, and one which is realistic.

I think we could design an ideal epidemiological study given that all the needed information was readily available in automated fashion. That's simply not the case. And, therefore, we have to develop a protocol that is both scientifically, epidemiologically adequate and is realistically faced with the problem of the nature of the records.

Dr. Carl Keller, who is with the National Institutes of Health Science -- Environmental Health Sciences, has kindly agreed to serve as Chairman of that subcommittee and has been working very hard with Dr. Hodder who's also an active member and a very valuable member of that committee.

We have had several meetings. And, I think Mr. Christian has been superbly cooperative and making all of

his staff available to that committee; has briefed them on a number of occasions; and, I think that we, at least, have a very thorough understanding of the magnitude of the problem, and have started on the -- on the road towards developing a cohort selection protocol.

Obviously, part of that effort has to be colored by what epidemiologists consider appropriate methodologies. So, we have in addition solicited the expertise of some other individuals -- biostatistical expertise, in particular. We're delighted that Dr. Richard Albanese who is working with Dr. Lathrop in San Antonio, has provided us with some guidance.

We also have had the services of one of our own VA researchers, Dr. George Fein from San Francisco, who came and spent some time with us, reviewing the protocol, and looking at the cohort selection process from a biostatistical approach. So, we have his report. And, we are also soliciting other experts in the field of sampling and biostatistics.

I hope that within the next month we will have an agreed upon cohort selection protocol; and, we'll be in a position to publish the RFP for the pilot study contract.

Yes?

DR. GROSS: A question: In view of the

difficulties which I can appreciate on this cohort selection problem, has there been any thought given to a stratified process by which individuals whose exposure can be well documented or better documented than those of others, would be included in some -- some stratum of such cohorts, which a certain weight could be given those whose exposure -- was less certain; there being another stratum for less weight. In other words, have a sort of a spectrum of exposure --.

DR. SHEPARD: Yes. Yes. That's one of the approaches that we're examining. The problem with that, however, is that even in the best of circumstances actual exposure levels/is in terms of -- of milligrams -- or micrograms. So, that level of detail, obviously, does not exist.

Some assumptions have to be made. And, one of the problems is that what is the actual exposure where does one put an individual on that continuum of exposure, and what data is available for that purpose, so that --

DR. GROSS: Well, I was thinking,more specifically, individuals whose service can be well documented to being in a certain unit that was known to have been exposed repeatedly. They would simply carry more weight, without necessarily giving a figure as to an actual

quantity of exposure.

DR. SHEPARD: Yes. We are doing that. And, again, I think Christian and his group have been excellent in identifying ways in which people were exposed. The problem that we have is we don't have a way -- I don't think -- of comparing what an exposure -- how various kinds of exposures will compare to each other.

For example: A ground troop who is serving in an area that's been recently sprayed: how does his exposure compare to somebody who is operating a backpack and spraying in a perimeter? Or somebody who may have been in an area in which there was a jettisoning? And, how do those exposures compare, one with the other. That's the sticky issue, I think.

Maurice, maybe you'd like to say more about that?

MR. LeVOIS: Exactly what you're suggesting is being looked at, along with two or three other modifications of the basic two cohort in Vietnam proposal that you have in the protocol.

Dr. Hodder, I would like to invite you to comment also. It might be appropriate for us to talk a little bit about what the subcommittee has discussed. I think we're actually quite closed to an agreed upon paper -- a methodology that has been developed by the subcommittee and will be transmitted through the

Agent Orange Working Group tp Dick Christian. I think that will happen in a matter of days or certainly in a couple of weeks.

Dr. Keller is writing that in a final draft; and, we'll all review it, I hope, pretty soon.

What's being debated, and has been all along, are such issues as our confidence in the categories in which we place the subjects. The possibility of his misclassification and particularly in this misclassification being one directional. We don't know to what extent that would occur. But, we suspect that we're more likely to put subjects in the unexposed category and make a mistake, than mistakenly putting subjects in the highly exposed category; because the highly exposed subjects would have met certain basic criteria.

They would have been observed to have passed through a ranch hand spray track and having an observed likelihood of exposure is a positive identification. Whereas not having it could be an error of omission. The exposure could have occurred.

And, I think this is what you're suggesting. There may be a way to stratify. One could, for instance, instead of looking at two groups, collect all of the exposure data on every individual that was sampled, and partition them into ten groups, and do some sort of non-parametric analysis; or, put the subjects in one

large group; not weight the exposure a priori, but simply do a regression and let the regression weight the exposure, to see whether or not -- for instance -- those subjects who were exposed to an abort happened to cluster around a particular outcome.

In other words, classify these things as categorical exposures and not as particular levels of exposure on a continuum. That, right now, is a -- is still a very serious problem for us, as Dr. Shepard has indicated. We don't know if an exposure to one backpack spraying operation is worth three and a half exposures to a ranch hand on day 2 at three kilometers. This is the kind of time - distance matrix that has to be set up for each one of these types of exposure.

And, we are not quite sure at this point even of the fundamental differences between modes. We're looking and have biostatisticians right now modeling such things as misclassification errors and its effect on different methods of analysis and its effect on the power to detect certain events; and the effect of misclassification on suppressing a true relative risk to an observed relative risk.

And, I think that all of this information is going to be very useful in tightening up the analytic part of that protocol, which has been commented on

previously as needing this type of work.

This is part of what the VA is doing through consultants and part of the problem that the subcommittee is grappling with.

DR. SHEPARD: Dick, do you have any comments on your reference with --

DR. HODDER: I think you've really covered almost all of the differentiation. Your point is quite well taken that you have to separate or stratify these people as much as possible. And, basically, that's one of the main -- that's one of the two real things we've worked on.

The second part of that -- Dr. Keller and Dr. Christian, and Mr. Maguire spent considerable time with us on this, is that in the process of getting the groups that far separate, that you're not producing a difference in the actual people -- demographic differences.

So, we have to make sure that the process of separating also maintains a random mix so that we're not picking an infantry group in the Highlands, compared to a group of medics on the Peninsula. And, that's -- those two simple principles take a rather large amount of work. You've got to challenge every assumption you make, continually, to make sure that you rule out an inadvertent-

DR. SHEPARD: Well, we are very pleased to have

with us a distinguished gentleman. First of all I'd like to introduce to you our newly appointed Deputy Administrator, Mr. Everett Alvarez. And, this is his first meeting with the committee. And, it's indeed a great pleasure and privilege to introduce him to you.

As you know, Mr. Alvarez has had a long and distinguished career in the U. S. Navy; himself served in Vietnam, unfortunately most of that time as a prisoner of war. So, I know that he has a deep seated commitment to the whole issue of Vietnam veterans and their concerns, and one of those, of course, being the concern about the possible health effects of Agent Orange.

With him is Mr. Derek Volker, who will address us; and, we're delighted to have him representing the Government of Australia. With them is Peter Shannon, who is one of the Secretaries of the Australian Embassy with whom we've been working very closely in a very cordial relationship.

And, now, I'd like to call on Mr. Alvarez to make a few comments.

REMARKS BY THE DEPUTY ADMINISTRATOR

MR. EVERETT ALVAREZ, JR.: Good morning, ladies and gentlemen. I appreciate very much the opportunity to be here this morning. Dr. Shepard has informed me that you have a rather full agenda today, so I'll keep my

remarks short, so that you can get on with your -- your activities.

I wanted to be here this morning to personally be with you and visit, and also to assure you of my support and my continued interest in your effort with your committee. This is a committee that has a very important function. And, I understand, it's a committee that has been performing this function in a very capable and efficient manner.

I want to thank all of you for the time and effort in attending these meetings. I know that these take quite a bit of time. But, you are doing it to provide us your talents, your expertise, and your thoughts concerning the serious issue of Agent Orange.

I also understand that the instructions, the quidance, and/the counsel that this committee has provided in the past has been useful and effective. And, it is appreciated.

This committee represents a multi-disciplinary group of professions of technical expertise. And, I want you to be assured that we value your advice. We look upon you as as a mechanism where we can air complaints. We can discuss ideas and especially the scientific data that surrounds the unanswered questions concerning the Agent Orange issue.

I am grateful to the agencies and the organizations that are represented by the members of this committee, for their cooperation and their efforts.

So, this morning I'm speaking to you, not only as the new Deputy Administrator of the VA, but also as a Vietnam veteran, who is deeply concerned about the many controversies that surround this issue. I strongly urge you to continue your work in a proficient, and most effective manner possible because we need those scientific answers.

I hope that the spirit of the work that you will have this afternoon -- today and this afternoon -- will generate new ideas, new initiatives, and new approaches to resolving or leading to the resolve of the Agent Orange matter.

Before I leave, I want to personally thank Mr. Derek Volker for joining us this morning. And, I'd like to introduce Mr. Volker, Chairman of the Australian Repatriation Commission and Secretary of Australian Department of Veterans Affairs. Mr. Volker has kindly consented to take time off on a personal visit to the United States -- to Washington, to spend a short time with us this morning in discussing the Agent Orange issues. So, Mr. Volker?

REPORT ON AUSTRALIAN ACTIVITIES

MR. DEREK VOLKER: Dr. Shepard, Mr. Alvarez, ladies and gentlemen. As Mr. Alvarez has said I've been on a private visit to the United States since the last few weeks. I got out of the habit of speaking publicly. So, you might have to excuse me if I'm a bit inarticulate for a while.

It's very interesting to hear Mr. Alvarez speak this morning because the sorts of things he's been saying to your Advisory Committee are precisely the sorts of things that we say to our Advisory Committee in Australia.

I suppose there are very few countries that share the need to explore the sorts of issues which are your concern, mainly because there were few countries that were involved in Vietnam on the side of what we might call the Allies. Many of the things that occur in the United States in the area of pesticides and the controversies and issues related to them and their effects on Vietnam veterans are reported in Australia.

Indeed, I think that any significant development in the United States probably does come to our attention in Australia. And, I'm sure that there is a very close liaison between the veterans organizations, as well as between the administrations in the two countries.

The issues in Australia, I suppose in one respect, are different from those in the United States, in that the

scale of our involvement, because we're a much smaller country, was smaller than the involvement of the United States. We had about 47,000 Australians who were involved in Vietnam over a period of roughly ten years.

In Australia, what we've attempted to do in looking after the interests of Vietnam veterans is, first of all, to use the existing procedures and mechanisms that are available. Some of these go back to the days of the First World War, so that we do have a Repatriation Commission, which is a statutory body with an ex-service organization's representative as well as two other members. And, the Chairman of that Commission is also the Secretary of the Department of Veterans Affairs.

We've encouraged Vietnam veterans to use the repatriation system. And, that system is intended to be generous in filing pensions, allowances, and other benefits under legislation. There was a decision last year -- you know -- in a high court case, the case of Nancy Law, which made it very clear that we had to grant benefits -- pensions -- in those cases where the Repatriation Commission could not demonstrate that, in fact, the particular disability was not related to the service. It's been called a reverse onus of proof.

So, that more than half of the claims that are now being lodged in Australia at the primary level -- the

first level of the Repatriation Boards -- are now being approved. And, if you go right through the whole of the system -- through the appeal systems, and there're various levels of appeals -- we're up to about 70 percent of all claims now being approved. And, that seems to be applying to Vietnam veterans, the same way as it does to veterans of other wars, even going right back to the First World War.

So far, about 7,000 of the 45,000 Vietnam veterans are receiving some of the pensions, together with about thirty and a half thousand of their dependents. These range from very small pensions for quite minor disabilities to -- what we call -- special rates for totally and permanently incapacitated individuals, plus of course widows pensions, where the veterans died.

In terms of herbicide related claims, so far we've been able to identify about 400 where in some way or another herbicides have been mentioned. And, of those, 364 have been approved; and, we've got about 250 still to be resolved.

I might mention that in the majority of those claims which have been approved, it hasn't really been necessary to look at the link between exposure to herbicides and the particular disabilities. But, I do emphasize that in some cases now, and particularly cases

which are going to our highest levels of appeals, chemical claims are being approved, mainly on the basis that the high court judgments that are referred to; makes it extraordinary difficult for the Repatriation Commission to demonstrate that the particular disability was not caused by war service.

That's the first thing is the repatriation system. And, as I emphasized, we are encouraging Vietnam veterans to come forward and make use of that system.

The second approach, and one of which I think you're very familiar in the United States, is by providing treatment for Vietnam veterans. We have a system of repatriation hospitals in Australia which is not as extensive as that in the United States, but nonetheless does provide treatment in -- in all our states. And, we have pretty elaborate system of local medical -- to provide treatment.

Now, in respect to Vietnam veterans, we've gone beyond the treatment facilities that are provided for veterans of other conflicts, by enabling those who have conditions which are not related to war service to obtain treatment in emergency or urgent situations. And, this has been extended to the wives and families of Vietnam veterans in those cases, where emergency treatment is -- is required.

So far, there hasn't really been much advantage

taken of those particular extensions of the normal benefits. It's not because people aren't aware of the existence of that extension. It seems, really, that at this stage, probably mainly because of the age group of the people there hasn't been a large requirement for people to seek that free treatment.

The third thing that is being done, and, again, this is very similar to what's happened in the United States, and to some extent has been based on the United States' experience, has been to provide an avenue for those who are weary of the bureaucratic system -- or the allegedly bureaucratic system of the Repatriation Commission and Veterans Affairs Department to be able to get assistance or counseling. And, we've set up a system of Vietnam veterans counseling centers in all our state capitals, together with Darwin in the Northern Territory. We're providing some extension outside of the metropolitan areas, to enable people just simply to drop in, as happens in the United States.

We've got trained counselors. We've got an extension system into the repatriation hospitals. And, that seems to be working pretty well so far, in the limited experiences that we've had.

I think what we've decided to do is apt to provide slightly more amenable types of premises, compared

with those in the United States; spending a little bit more money on the physical arrangements and also ensuring that we have very good quality people who do know what they're talking about.

Because, of course, one of the worse things that could happen is that you've got people who are providing counseling in the systems and information -- who don't really know what is the right sort of assistance to provide. So, we've gone to a lot of trouble in that respect.

Turning particularly to the question of herbicides, I suppose we should talk about pesticides because there seems to be a trend in Australia to talk more about insecticides, rather than herbicides.

The first thing that has -- that has struck us -- as a new boy, I've only been in the job for about 10 months -- was that there was no accurate data base about the -- the incidence of deaths, certainly of birth defects, and of the various disabilities and incapacities among Vietnam veterans. There are some statistics that have flung around the place by various groups in the community which seem to indicate that many Vietnam veterans are commiting suicide and many others have cancer, and so forth.

I think it's -- can be unfortunate the statistics are thrown around because it gives the impression in the community, generally, and among employers,in particular, that Vietnam veterans, as a group, do suffer a very high incidence or an extaordinarily high incidence of disabilities. Of course, that can affect their chances of employability; and of just generally fitting in the community, generally.

So, we're trying to get an accurate data base. And, I've written recently to the President of the Australian Vietnam Veterans Association to try to get an agreed data base on exactly what has been happening with deaths, suicides, deaths from cancer, and so forth. And, I hope that that may lead us to be able to agree, at least, on what has been happening and what is happening.

As far as we can see from the statistics that we have -- that we've collected from a variety of sources, so far -- there doesn't seem to be generally much difference between the incidence of suicide or deaths from cancer, -- Now, I use that in a very broad sense -- among veterans and among the age groups of -- in which Vietnam veterans generally find themselves.

But, I do emphasize that the data base is deficient; and, that we're only talking about the information that we have available to us in the present.

In addition to that, the government has decided that it would undertake some studies. Originally, it was decided that there would be a major epidemiological study, which would involve all the Vietnam veterans, their families, and extensive and necessary control groups.

After undertaking part of a pilot study and going over the data that had been obtained, and looking at the methodology, it was decided that it was not necessary to undertake such a broad based epidemiological study, which would have taken a very long time; and, although this is very much a minor matter, would have been extraordinarily expensive.

Because it was possible to obtain at least as valid conclusions from a smaller study or a number of smaller studies; and, the government earlier this year decided that it would undertake two specific studies: One on birth defects among the children of Vietnam veterans; and, secondly, on mortality.

The birth defect study should be -- the conclusion should be available by the end of this year, hopefully by the end of November. The mortality study conclusion should be available by the end of next year.

And, the third thing it was decided to look at was a protocol for a -- study, which would be based upon a sample -- a necessarily sized sample -- to enable valid

conclusions to be drawn. We're still getting the information and the method of -- methodological protocols for that morbidity study. It is not possible at this stage to be able to talk more of -- in more detail about that.

The final thing that I'd like to say is that there has been a senate inquiry into pesticides in Australia; and the first part of that was concerned with the effects of possible exposure of those who served in Vietnam to the pesticides. Its conclusion -- its hearings-- I think it's now in the process of preparing its report. Hopefully, that report should be available within the next month or two.

In the course of that inquiry, of course, the Vietnam Veterans Association of Australia gave extensive evidence, together with evidence from their experts, from government sources, and from the community generally; and, clearly, I'm not in the position to be able to indicate what that independent center of inquiry will determine or what its recommendations will be.

But, we are, within the Repatriation Commission and within the Department, looking forward eagerly to receiving the results of that inquiry.

Related very generally, Mr. Chairman, the things that we're doing in Australia: I did mention that we -- we

have a National Advisory Committee in Australia, which is concerned mainly with -- really running the Vietnam veterans counseling service. And, that committee has representatives of the Vietnam Veterans Association of Australia, the Commission, some outside medical experts on it. And, it's a small body, as far as I can see, than one that you have. It was for a smaller country and the issues are smaller, so that we can get by with a smaller number of people advising the Commission.

I do welcome the opportunity of talking to you. I wasn't aware that there was going to be media presence here today, so that, perhaps, I haven't prepared as quite profiled -- as resume as I might have done in other circumstances. But, it is -- it is a great honor to be present. We look forward to sharing further with you information that becomes available. And, also, I think, sharing information about activities that are helpful to Vietnam veterans, and, indeed, to other veterans as well.

And, I think the more that we can share our experiences, not only in terms of what is successful, but also, in terms of what is not successful; so that we're not inventing the wheel simultaneously in two countries. I think the better for all concerned.

Thank you very much, indeed.

DR. SHEPARD: Thank you very much, Mr. Volker.

I would just like to cap that by -- by announcing, as I'm sure you're aware, to the committee, that approximately three - four weeks ago we had the pleasure of having a conference call with Dr. Bob Walsh and Dr. John Gotlin, and other members of the Advisory Committee, and other scientists in Australia. A number of us sat in my office upstairs. And, we had an excellent connection, I suspect via satellite, with a group in Australia; and we discussed issues for the better part of two hours.

So, I think we have a much clearer understanding of your efforts and a keen appreciation. And, it was remarkable the similarity between issues that faced your group and those same issues that faced our group. And, so, it continues to be a very rich source of information and a cordial relationship. And, we really look forward to continuing along those lines.

We certainly appreciate your being with us today. Thank you, Mr. Alvarez. We appreciate your being here, too.

We'd like to move along on the agenda, and next call on Dr. Al Young, who can tell us a little bit about another exciting effort in the offing, that is the Third International Doxins Symposium scheduled to take place in Salzburg, Austria, next month -- the early part of October. Al?

INTERNATIONAL DIOXINS SYMPOSIUM

DR. ALVIN L. YOUNG: Thank you, Dr. Shepard.

Since 1980, there has been an International Symposium each year, dealing with the questions raised by exposure to the Chlorinated Dibenzo Para Dioxins and Dibenzofurans, related compounds. The first International Symposium was held in Rome in 1980. The VA was represented by Dr. Shepard.

Last year, we were fortunate enough to have the 1981 International Symposium in Arlington, Virginia. Three hundred scientists from throughout the United States and the world assembled there. We had three days of intensive discussions on the status of the science related to dioxins and furans. I would just point out that the publication from the first symposium, the 1980 symposium, was published last year. The 1981 symposium proceedings are coming out this next month. It's a volume entitled, Human and Environmental Risks of the Chlorinated Dioxins and Furans. Plenum Press, New York, is releasing that; and we expect it around the end of September.

The 1982 International Symposium on Dioxins and furans is going to be held in Salzburg, Austria, on the 12 through the 14 of October; a tremendous location. Those of us fortunate enough to be able to go are quite excited about it. I would just point out that the program is going to be very exciting.

Last year, in Arlington, we spent a good deal of time talking about the health programs or projects that were underway. Unfortunately, in Salzburg, we're not going to be able to hear the results of very many of those studies. It's going to be in the 1983 program for Montreal where the results from these major health studies will probably be released.

There will be a few health studies being released in Salzburg, but,unfortunately, most of the health studies that are underway simply are not completed yet.

The major emphasis in the Salzburg meetings will deal with chemistry and with sources of dioxins. We know now that, not only do certain pesticides contribute to the presence of dioxins in our environment, but other sources contribute these contaminants. For example: Incineration, may be even more important in terms of how much dioxins are released into the human environment than the use of certain pesticides. And, it will be the Salzburg presentations that deal with the handling of incinerator generated dioxins and various episodes involving waste disposal -- discussion of Love Canal, and discussion on the Bingington fire in Bingington, New York.

So, the primary emphasis of the Salzburg meeting will not be human, but rather related to some of the aspects of other sources of dioxins and furans in our environment.

There will be one afternoon devoted to

epidemiologic studies; and, Dr. Shepard is the Chairman of that particular section. The Air Force has indicated they would be ready to release information concerning the ranch hand mortality study.

Dr. Raymond Suskind, Cincinnati, Ohio, will be talking about a morbidity study of workers involved in 2,4,5-T production and associated contaminants. This is the Nitro, West Virginia Study. He's going to be presenting data, morbidity data, on an accident that occurred more than thirty years ago. He's been able to follow some 500 workers during this time period. Those results should be very, very important to us.

In addition, we're going to have an excellent update on the Seveso, Italy accident, and a number of scientists from Italy will be at the Conference to talk about it.

We're also going to have Dr. V. Riihimaki, from Helsinki, Finland, talk about the studies of soft tissue sarcoma, that have been going on in Finland. Very interesting. The Finnish studies are studies that are finding different results than the Swedish studies on the subject of soft tissue sarcoma. So, we're going to hear two points of view on the soft tissue sarcoma issue at Salzburg, and that should be very interesting.

Between now and the Salzburg meeting, there will

be another Symposium on dioxins. Now, everybody says another Symposium's. Well, I'm reminded yesterday on the morning news of an individual that said all the answers are in on the dioxins. Now we can settle the question!

But, the truth of the matter is that we're just beginning to understand a lot of the problems related to dioxins. A Symposium that the American Chemical Society is sponsoring in September, 14 through the 15, is going to deal with "Chlorinated Dioxins and Dibenzofurans in the Total Environment." I brought copies of that program for the committee and some additional copies for the audience if they want them. I would only like to highlight a couple of the presentations that are going to take place in Kansas City, then, on the 14 and 15 of September.

There are a number of things that will be talked about and Dr. Hardell from Sweden will be there. And, he's going to talk about further work on the soft tissue sarcoma studies in Sweden.

There will be a couple of studies that address occupational exposure to the chlorinated dioxins by Dr. Rappe, of Sweden.

There will also be a number of studies dealing with the identification of the 2,3,7,8-TCDD isomer in human tissue. Recent interest in blood analysis, looking

for the 2, 3, 7, 8 isomer, has come to light and some results are going to be available on that.

Well, very briefly, Dr. Shepard, that's the scientific aspects related to dioxins over the next few months.

DR. SHEPARD: Thank you very much, Dr. Young. Are there any questions for Dr. Young from members of the Committee?

Unfortunately, I will not be able to attend the Kansas City meeting. The Veterans Affairs Committee will be holding hearings on one of those days. And, I happen to be on hand for that.

However, I will be looking forward to Dr. Young's report of the Kansas City meeting, because I think it will likely have some material of great interest to us.

Senator Berning?

SENATOR KARL BERNING: Yes. One question. You mentioned incineration as a source of dioxins.

DR. YOUNG: Yes, sir.

SENATOR BERNING: What, to your understanding, would be the generating of dioxins from volcanoes?

DR. YOUNG: Well, you're going to have to have a good source of chlorine. And I'm not aware of any work related to volcanoes and dioxin fallout. But, dioxins are

formed in a combustion processes. In this case, you probably have temperatures that are going to be so high that you would not have to worry about sources of dioxins from volcanoes.

It's low temperature incineration that results in the formation of dioxins. Municipal incinerators that simply don't reach high enough temperature for their destruction that can, in fact, form the dioxins.

SENATOR BERNING: Thank you.

DR. SHEPARD: It's an interesting question. I suspect maybe Al Young is already itching to go out to Mount St. Helen's, and sampling the soil out there.

But, there are, of course, organic compounds that are combusted in that process, and there may be actually deep deposits in the soil that are organic -- St. Helen's. Very interesting question, Senator.

Senator Berning of Illinois will be addressing us a little later.

Now, Dr. Young, we'd like to hear a little bit more about the efforts that you've been helping push along in the area of Monograph Series. Can you tell us a little bit about where we stand in that area.

VA MONOGRAPH SERIES

DR. YOUNG: As you can tell, I get enthusiastic over a lot of issues. Again, to me, one of the

enthusiastic things is an effort we're now putting together to gather information on various issues a Monograph Series.

For example: A lot of our Environmental Physicians have wanted to know more about chloracne. And, so, we've been out talking to a lot of the experts, not only in the United States, but worldwide, about the possibility of assembling a volume with description and photographs on chloracne. And, indeed, we are now beginning to put together that group of experts to assemble a monograph.

I had hoped to be able to tell you that we got everybody on board by today, but we haven't yet. But, we are proposing and going through with contacting individuals for a monograph on chloracne.

Recently, when I was in Wisconsin, this past week, there was a lot of concern and questions about genetic screening and genetic counseling.-- the whole birth defects issues, and we're all very much aware of.

So, we have, indeed, proposed a monograph on birth defects, genetic screening and genetic counseling. And, we are currently looking at two individuals, experts in this area, to do that monograph now. We have already received from one of them an in depth outline of a proposed monograph on genetic counseling, birth defects, genetic screening. So, that's another monograph.

We have already started a monograph on Cacodylic Acid, Agent Blue. And, that monograph is being done by one of the real experts in the area of Cacodylic Acid, Dr. Ronald Hood, at Tuscaloosa, Alabama. That monograph is very exciting to us, because a lot of information that we've asked for on Blue will be assembled there. I'm not only talking about military use of Cacodylic Acid, but also at the chemistry; the environmental fate; and some very recent toxicology data.

Dr. Hood is a recognized, worldwide expert in the area of toxicology of Cacodylic Acids. And, we're very excited about this Monograph.

We're also looking now into a monograph on military insecticides. Mr. Volker brought up the issue of Malathion an issue that hasn't gone away, despite the Medfly applications in California. Chlordane, DDT, were also used in Vietnam. We have been in touch with the Armed Forces Pest Management Board, and they're providing us information and some specialists that will be available, we hope, to prepare a monograph on the use of insecticides in Vietnam.

Another issue that has come up is related to soft tissues sarcomas -- and, indeed, we're now looking into that as an inclusion into the monograph series.

Basically, the format of these would be as follows:

They'll be published by the Government Printing Office, and they will be in a hard cover, bound publication. And, we're going to make them a series-- the Veterans Administration Monograph Series. We're looking at some first class pieces of work here -- the photographs, good diagrams, pieces of scientific documentation that will be of value, not only to our environmental physicians and our staff members, but to the entire scientific community and the public at large.

We hope to have the first monograph -- the one on Cacodylic Acids will be out early in the spring. And, I'll keep you informed of how they progress and who the authors will be as we make the selections on them.

DR. SHEPARD: Thank you very much, Al. I'd like now to call on Dr. Nelson Irey, from the Armed Forces Institute of Pathology, who will give us an update on the AFIP Agent Orange Registry. And, perhaps, we'll discuss some ideas he's had about further research using the tremendous resources at AFIP. Dr. Nelson Irey.

AFIP AGENT ORANGE REGISTRY

DR. NELSON IREY: Thank you, Dr. Shepard.

Members of the Committee, ladies and gentlemen: Four years ago at the Institute a registry was started of surgical and

autopsy material from Vietnam veterans, with the object of attempting to find out what the current illnesses of this group were.

We also included findings revealed -- revealed at autopsies. This is a report on the first 800 cases in this Registry.

May I have the first slide, please?

(Slide No. 1)

This shows a distribution of the ages. Notice the dominance of the 30 to 39 decade, which, if you push back 10 years, plus or minus a few, indicates the dominance of the younger age group in the Americans assigned to Vietnam. And, it's a fairly smooth curve. It starts low, goes up, and then recedes in an orderly fashion.

(Slide Nos. 2 - 5)

These four slides show the demographic data. Males predominate; the few females were nurses. In 40% of the cases, the race is as yet unknown. Over 90% were biopsy specimens. About 5% were autopsied cases, and 5/800 had both biopsy and autopsy material for evaluation. There were 70 involved organs or sites, showing a wide

anatomic distribution of lesions. There was a similar wide geographic distribution, casew being submitted from 43 states. The VA hospitals submitted 88% of the cases, the remaining cases coming from civilian and Armed Forces installations.

(Slide No. 6)

We tabulated, particularly, cases relating to skin, liver, and benign and malignant tumors. This slide is a summarization of the dermatologic findings Chronic dermatitis dominated, with 14 variants. We did have two clusters, epidermal inclusion cysts, and lipomas. Both are minor pathologically and without any serious prognostic significance.

Their high incidence may be related to the fact that both lesions are visible and palpable; and, to the concerned veteran, they represent tumors. And, nobody knows what they are until they're excised.

The remaining 40 skin diagnoses had 6 or less cases per diagnosis.

(Slide No. 7)

The liver group constituted 43 cases. Twenty-six of the 43 cases were documented as being alcoholics, drug abusers, or both.

For instance: In the Fatty Metamorphosis group, there were 5 out of the 12 that were in these two special categories. In the cirrhosis group, there were 7 out of the 8 that were either alcoholics or drug abusers.

(Slide Nos. 8 - 10)

The benign tumors constituted 14% of the 800 cases. Lipomas (59 cases), and dermatofibromas (18 cases) were the largest single diagnostic entities, together making up two-thirds of the benign tumor group. Papillomas of the skin and polyps of the G-I tract were the next most frequent benign tumors, followed by a few adenomas of the colon, and one adenoma of the salivary gland. There was finally a miscellaneous group of benign tumors, including a few tendon sheath and peripheral nerve tumors, with single instances of vascular and skin adnexal lesions.

Except for the lipomas and dermatofibromas, there appeared to be no significant clustering of any of the other tumors.

(Slide Nos. 11 - 16)

The malignant tumors constituted slightly over 10% of the 800 cases. In order of frequency, by site: skin, lung, lymph nodes, G-U tract, G-I tract, and a miscellaneous group, including lip, liver, eye, peritoneum, and salivary gland. About two-thirds of the tumors were in the carcinoma category. The remaining included reticulo-endothelial malignancies, soft tissue and bone sarcomas, and tumors of the central nervous system.

The most frequent diagnoses were basal cell carcinoma of the skin (13), Hodgkin's disease (8), lymphomas (6), adenocarcinoma of the lung (6), and colon carcinoma (4). The remaining 35 diagnoses were made three times or less. Thus, there appeared to be no significant clustering of unusual diagnoses in unusual sites. Six of the cases in this malignant group had unusual features, but occurred only singly. These included one prostatic carcinoma in a 44 year old; one case with metachronous tumors (2); and a lung cancer in a 31 year old male. In this phase of our study, we are particularly looking for clustering of unusual diagnoses. This is on the basis that at least some environmental chemicals do just that. Examples include: vinyl chloride and liver angiosarcoma; and asbestos and pleural mesothelioma.

(Slide No. 17)

This slide compares the relative incidence of malignancies in the Agent Orange group with the national experience in males, in the five most frequent sites of tumor occurrence. Note that the relative incidences correspond except for the 2nd and the 5th entrees: the prostatic and lymphoma groups, which are reversed. Since most of the Agent Orange veterans are in the 30-39th decade, they have not as yet entered the prostatic cancer period, hence this is the least frequent tumor. The lymphoma group is relatively frequent in the Agent Orange Group because, with their dominant youth, they are in the first of the bimodal frequency for reticulo-endothelial malignancies.

(Slide Nos. 18 - 19)

These list the most frequent of the remaining diagnoses made on these 800 Vietnam veterans. The largest group was the "negative" or "normal". The ten next most frequent diagnoses include hernial sacs, menisci from the knee, gall bladders, appendices, herniated intervetebral discs, reactive lymph nodes, pilonidal cysts, and foreign body reactions from a variety of sites. Included was a group in which the material submitted was considered "inadequate for diagnosis". The remaining 103 diagnoses had six or less cases per diagnosis. This spectrum of diagnoses was wide, and without significant clustering, so that again this study failed to reveal unusual features.

(Slide No. 20)

There might be biases in case selection. To avoid this, we have asked the pathologists who are contributing material to use only one criterion, service in Vietnam, and otherwise be non-selective. In other words, they're not selecting just the tumors and the odd and unusual cases.

The fact that we are receiving hernial sacs and menisci and appendices and gall bladders, in which there's little chance that an environmental factor in Vietnam could have played a part indicates compliance with this selection criterion.

Diagnostic bias: We have two pathologists in the Registry. We can't know everything about every area of pathology, and it's our practice in almost every instance to submit the case in consultation to the appropriate anatomic area within the Institute; so that your're not getting opinion from just two pathologists.

Geographic bias: The source of cases, as I mentioned, was from 43 states, certainly a wide geographic base.

Institutional bias: We're receiving case material from about 100 of the VA hospital network, which certainly represents a wide hospital base.

(Slide No. 21)

While we are getting a wide spectrum of surgical diseases, we're not addressing problems relating to teratogenesis, fertility, mutagenesis, or neuro-behavioral problems. We can address the problems of carcinogenesis, and, of chronic toxicity such as those who might have had an acute phase of liver toxicity in Vietnam and survived and who now might be showing chronic hepatic changes. Also, we are not addressing medical problems which do not have biopsy material. With these caveats we are able to say at this point that, as reflected in the biopsy and autopsy material, we have not seen unusual features in this group of 800 cases.

A few more points: We have an additional 250 cases that are completed that will be incorporated in our tabulations shortly. There are an additional three or four hundred cases that are in various stages of processing in our Registry. We estimate that by the end of the year, we should have between 1500 and 2000 cases in the Agent Orange Registry.

In our initial material received from contributing pathologists, it's not unusual for age, or sex, or race, or Vietnam dates of service to be missing. So, as we report back to the contributing pathologist with our diagnostic opinion, as we do routinely, those missing items are requested.

We have recently reviewed 250 of these responses from contributing pathologists. In regard to Vietnam service, we found that 70 percent were confirmed, 20 percent were ambiguous, and, 10 percent had not ever been in Vietnam. We must now go back and eliminate the group that we have definite evidence of negative Vietnam service. And, we must attempt to get positive documentation of service in Vietnam in all cases.

I think what we will do is turn over the names and Social Security numbers and hospital source to the central headquarters, and ask the VA to either confirm or deny that these people were in Vietnam.

Thus, by the end of the year, we hope to have a hard core of documented Vietnam service veterans in this series.

While this study has not as yet shown unusual features that might mean Vietnam-related illnesses, it seems advisable and necessary to get a matched control set of non-Vietnam veterans (Phase II), to allow comparisons between these two groups as to the more usual diseases, their incidences and sites of involvement. Similar pathological material from non-Vietnam veterans, matched by age, sex, and race, could be obtained from the same VA hospitals that furnished the Phase I case material; the time period would be the same: 1978-1982. Appropriate statistical studies could then be made between the findings in these two groups.

We'd like to ask the Committee two questions. Number one: Is 1500 to 2000 cases in this project a sufficient number from which to draw conslusions? Are we reaching the point of diminishing returns beyond that? Or, would the Committee recommend a larger number of cases?

And, secondly: Do you agree that a matched control set of non-Vietnam veterans should be obtained for statistical comparison with the Vietnam veteran group?

I've asked Dr. Walter Foster, who is the Institute's statistician, to come to the meeting this morning. He is here and available for questioning.

Thank you.

DR. SHEPARD: Dr. Foster, is he here?

DR. IREY: Yes.

DR. SHEPARD: Why don't we have him come up?

Well, thank you very much, Dr. Irey. I think this is an intriguing idea. And, I would encourage questions from the Commitee and also responses to -- up to the front as to Dr. Irey's two questions.

Yes, Dr. Fitzgerald?

DR. THOMAS J. FITZGERALD: Dr. Irey, from your statistics, so far, I gather that you have not seen an unusual incidence of soft tissue sarcoma?

DR. IREY: That is correct. We do have a number

of sarcomas, but they are in single instances as to their location and with no clustering.

DR. FITZGERALD: To answer your question that you just related to members of the Committee, concerning the continuation of the study, I think it would be important to continue the study if for only one reason: And, that would be that as the age of the veteran increases, you would anticipate that you might see more end results.

DR. IREY: Yes. The longer the lapsed time after Vietnam service, the greater the likelihood of tumors showing up, if there were carcinogens in the Vietnam environment. Periodic re-opening of this project might be done at intervals of 5 - 10 years, to monitor this point.

DR. SHEPARD: Yes, Hugh?

MR. HUGH WALKUP: You're dealing with a layman, so I'll have to break it up, down in layman's language. But, from the way you were saying, it sounded as if without

the tests opf statistical significance and without the control group that you are proposing or without matching it with parameters of the total p[opulation, it's not possible to make any firm conclusions off the data that you've collected. This is indicative only, is that correct?

DR. IREY: We can make a relatively firm conclusion, at this point, that there are no unusual features about the findings that would thereby implicate Vietnam service as a likely cause of any of the diseases. However, while environmental chemicals may produce unusual illnesses, they may also produce quite ordinary diseases in common sites. With a matched control set of cases without Vietnam service, these more common and usual illnesses might be monitored for. To get back to your question: yes, we can say as a conclusion at this point that these 800 cases do not show unusual features that might suggest a relationship with Vietnam service. What we cannot say, without proper controls, is that there are no common diseases that might not be related to the Vietnam environment.

MR. WALKUP: And, in relating your first question about how many is enough, could I ask you that? At which

point would say that you had enough data to be able to make a firm conclusion, as far as the unusual in the study?

DR. IREY: I defer to the statistician.

DR. WALTER FOSTER: We have thought about that question loud, long, and over quite a number of cups of coffee. It is not an easy question, and it's primarily related to incidence rates themselves, in terms of how rare the disease in a particular location; such that, with a file of, say, 800 now, or, say, 1500 by the end of the year, out of that denominator of the 1500, what kind of incidence is required to get, say, a meaningful number of these -- an occurrence of one; would it be an occurrence of two?

If you get a misclassification, which has always been a problem, what happens to a statement of, say, significance in something like that?

So, clearly, I think that, in terms of the rare diseases, we're not anywhere near it. And, I think we would have to be -- oh -- a thousand times the size of our file to be into the rare diseases.

But, getting back to the common diseases in common locations, as a possible magnification because of dioxin exposure, then, we would need the matched control. So, I -- I think to go into something that's this rare, in terms of frequencies, we're clearly not anywhere

close to it.

And, I think that the FIP might be overwhelmed if it were asked to be there. But, in terms of the matched control, phase 2, perhaps, we can see if there are augmented frequencies there.

So, the number of how many should we have is sticky. And, I think that about where we are could be very helpful. But, to go further, would require a very, very large effort.

DR. SHEPARD: Yes, Dr. Cordle?

DR. CORDLE: But, it seems to me that the important thing here is not how many you necessarily have in the group they're talking about, but how well does that group represent the veterans who are dying, who were in the Vietnam era? And, that's where you're going to have to do your statistics, I think, to see what your sampling areas and everything might be.

Do you have any estimate at all of how this represents the total number of veterans who are, in fact, dying and from the group from which your samples come?

DR. IREY: I don't think I can answer that. I can only say that the VA

has asked their pathologists to submit to us diseased tissues removed at surgery, and

autopsy specimens from Vietnam veterans.

To a degree, that's representative of what the practice of medicine in the VA hospitals is now, relating to Vietnam veterans. I can't say anything further.

DR. FOSTER: I might repeat something Dr. Irey did once before on one of the slides. He had a ranking of the diseases that we have discovered in the Agent Orange Registry at AFIP, versus a ranking of about the same age group over the U. S. population, in terms of occurrence of disease. And, the rankings were highly coincident in this ranking procedure. (These figures do not refer to actual frequencies, of course.)

And, the thrust of that remark is that the rankings were almost identical -- well, they were identical, except for the reversal of 2 and 5, prostatic cancer and lymphoma.

DR. SHEPARD: Just from my perspective, I would say that there is very little way that we can represent this as -- as representative of the Vietnam population. And, the best we can say is that this is a cross section of Vietnam veterans who present themselves to VA hospitals for care.

As we get a large enough group, I guess we can make some descriptive statements about what kinds of problems this group is revealing. But, to try to

make any judgments, in terms of the representativeness of this group, vis-a-vis the whole Vietnam veteran population, I think it would be very difficult, certainly at this time.

I don't think that's been the intent on that. In that regard, has some of the same problems as the Agent Orange Registry. We have no feel for how representative the Agent Orange Registry is for the whole Vietnam population -- service population.

DR. CORDLE: Given that as the way the real design of the study it's extremely important that you have a matching group with this group.

DR. SHEPARD: I'd like that, too, solicit some comments about the idea of having a matched group on Vietnam era veterans who did not serve in Vietnam; and, maybe, some of the methodology that would be satisfactory for developing such a matched group, because I think that's where we would have to go, unless, as indicated, you have a huge number of individuals. I wonder if we could spend a few minutes discussing the pros and cons of developing a matched group and how one would go about doing -- Dr. Irey has been wrestling with that question for some time now. And, so, I would solicit. Dick, do you have any thoughts on that?

DR. HODDER: The difficulty with

a control group is: Normally, when you talk about a control group, you start with people who have a specific disease. Then you find others who don't and see if they differ in some way.

What you're controlling for here is really, whether your pathologist calls that person a Vietnam veteran or not. It's not the typical thing you would do with a survey.

What Dr. Irey's Registry does is give an index of an unusual occurrence of, hopefully, somewhat uncommon diseases. I think that this approach is fairly insensitive on common diseases, because you don't know how to handle the representativeness of your sample.

But, if you suddenly had a large number of amgiosarcomas of the liver, or something else unusual, that would be a clear touch stone to do something about.

You could use a control for two things, either to follow up a specific disease, or to use a control to give you an idea what the selection problems might be. from the veteran's hospitals. But, that, again, does not really get into how representative that is in the general population.

DR. SHEPARD: Any other comments to make? Yes, Dr. Gross?

DR. GROSS: Dr. Irey, I notice that there are a couple of pages here of detailed diagnoses with rather low frequencies, particular near the bottom of the pages, I was wondering what thoughts are given to combining some of these diagnoses, along rational, pathologic lines? And, would this not make this whole distribution more efficient, as far as detecting broad classes of pathology entities?

DR. IREY: We consolidated the malignant group and came up with an eleven percent number in the 800. We consolidated the benign group. That came out to 14 percent of the 800 cases. I haven't done that for the skin group.

It is possible, of course, to put these things together. Now, I've talked to the dermatology people about this wide distribution of low frequency diagnoses. And, they defend their splitting tendencies, as to that's what it is. I suppose they could be consolidated into inflammatory and metabolic categories to some advantage.

And, of course, if we got a control group, that will be an interesting way of running a comparison, down the line, with the two matched up.

DR. GROSS: Well, I wondering whether there is some sort of -- I hate to call it policy, but -- some sort of procedure at the AFIP for listing pathology diagnoses into higher classes, less and less specific, more and more inclusive. Is there some such procedure to discover differences in different populations, which may be less specific, but more frequent?

DR. IREY: Well, we haven't done that here, yet. I'm sure that this would explored in particular areas, like in the dermatology group and in the malignancies.

DR. SHEPARD: Thank you. I would like to ask you a related question that just popped into my mind. As I indicated earlier, we have plans underway to sample the Vietnam era population, as it exists on the VA patient treatment files.

It's been suggested that in that sampling file -- we have not yet established the parameters of that sampling. -- so, as I said, the RFP for this contract has just gone out. we will provide names to the contractor, and he will simply identify whether or not that individual served in Vietnam. That will be the substance of the contract.

The contract will not adjust itself to sampling methodology. We still have it within our purview to set up the parameters of that sampling process. Now,

let me just make sure that everybody understands. There are several thousand Vietnam era veterans treated in VA hospitals each year. The fact of period of service is designated in the patient treatment file. The fact of service in Vietnam is not so designated.

We will have a contract to make that distinction, based on a review of service records.

I would like the Committee's thoughts on whether or not we should look at specific illnesses, as they exist diagnostically in the patient treatment file, and attempt to review a hundred percent of soft tissue sarcomas. There probably are not that many in the patient treatment files, so we would not overwhelm the contract with having all the soft tissue sarcomas.

But, it seems to me, the opportunity exists for doing some of those kinds of things. If there are other illnesses of particular concern that are not so common -- so frequent that -- that we'd be doing just that particular diagnosis.

So, I don't necessarily need an answer right now, but maybe you could be thinking about that. And, it would be very helpful as we develop strategy for this PTF sample methodology to have your input on that.

DR. IREY: One of the points of this study,

within this Vietnam group was to bring out, if they're there, clusters which would draw our attention to certain areas that we would then focus on, and study in more detail, and get out more cases of that particular category. That was one of the functions that this study presented as a potential.

We have not found such a focusing, as yet.

DR. SHEPARD: Well, thank you very much, Dr. Irey. I think at this point we'll take a very short break. Let's all reassemble at twenty minutes of eleven.

STATE ACTIVITIES

DR. SHEPARD: Can we come to order again, please? I'd like to call the second portion of the meeting to order, and introduce to you Senator Karl Berning -- I hope I pronounced it correctly -- from the state of Illinois. Senator Berning is heading up the Agent Orange Study Commission for the state of Illinois; and, we welcome him here this morning with a great deal of pleasure. Senator Berning.

SENATOR KARL BERNING: Thank you, Dr. Shepard, and members of the panel. We,of the Illinois Agent Orange Commission, appreciate this opportunity to appear before you and share some of our views with you.

For the edification of all of you and for the

audience, I'd like to introduce two of our Commission members who accompanied me here: Commissioner Joan Maiman, who is known to many of you - Joan; and Commissioner Ed King.

I don't think I have to remind any of you that I am not a Vietnam veteran. However, we in Illinois have been much concerned about the plight of the Vietnam veterans in our state, and,obviously, throughout the United States.

Prior to this meeting, and some feedback that we have had from the VA, many of us in Illinois seem to have the feeling that correlated with the observations of one of our Southern Illinois farmer friends, who, one day for the first time, visited a zoo. He stood there for quite sometime looking at that tall, long neck thing -- a giraffe. He turned around on his heel and he spat, and he said to his wife, hell, there ain't no such animal.

That's about what we felt was the attitude, up until just recently, of the federal government and the VA about the Agent Orange problem. Now, let me hasten to point out that I'm not interested in critizing or attacking. But, we in Illinois legislature represent all of our citizens, and we feel there's been too much delay in facing up to what, to many of us, is an obvious problem of huge dimensions.

Continued studies of the type that have been

discussed here, we agree are necessary. The various aspects of the Agent Orange problem are manifold and the studies are necessary and should be continued. However, I remind you,gentlemen, ladies, that while you and I are talking men and women, our fellow citizens, are suffering and dying, now

and, from what we have had in the way of testimony, with little or no help from their government. Even on occasion, all too often, treated with abuse and contempt by the VA, according to the testimony we have received in duly convened Agent Orange Commission hearings.

We have a few questions. One of them has been touched on, here, briefly. In light of the VA's persistent statements that only the lack of available human evidence prevents them from acting; information contained in the epidemiological studies from Sweden and Germany, as an example, showing the carcinogenicity of 2, 4, 5 T, should assume an overwhelming significance, in our opinion.

And, we respectfully suggest that studies which are considered here ought to start from, perhaps, what is already available.

Time won't permit recounting all of the questions that have arisen in our hearings and the investigations, therefore, let me recite just a few for you, perhaps to encourage the cooperation of the VA to assist the Illinois

Agent Orange Study Commission to achieve our objectives; and, I think you've been furnished with a synthesis of the charge which is contained in our enabling legislation.

It would be most helpful if you, Dr. Shepard, and your environmental physicians would share your expertise in environmental medicine with us.

Number one: Although the VA has persistently stated that TCDD exposure causes chloracne, does the VA pay compensation to veterans suffering from chloracne without references to a rash specifically found in the veterans military records? And, I point out to you that there are, at least in Illinois, serious gaps in the availability of the veterans records because of an unfortunate fire in St. Louis.

However, that doesn't minimize the problem of the veteran from whom we hear. So, I say, will the VA acknowledge causation in claims paid for chloracne?

Two: Given the studies already available, why is a specific study on Vietnam veterans necessary? I defer to the expertise of those professionals from whom we have heard -- and I must say I'm impressed with what is the obvious interest, but I'm inclined to reiterate that we representing our citizens and those who served in Vietnam, and listening to their stories, don't want you to get embroiled in only technological and scientific

investigations that tend to push aside and forget the urgency of the situation that confronts our fellow citizens.

If the VA rationale is that veterans -- Vietnam veterans may have been exposed to -- 2, 4, 5-T in a context other than Vietnam, cannot the VA determine through its normal adjudication processes, whether a Vietnam veteran's chloracne may have been caused by post service exposure. In other words, let's define it.

There are many questions our Commission members would like to discuss with the VA, including evidence and reports from governmental agencies, such as EPA, FDA, HEW, Department of Agriculture and Dr. Young's presentation this morning.

On behalf of the state of Illinois Agent Orange Study Commission, I extend an invitation to you, Dr. Shepard, to participate in some of our future hearings for the purpose of first helping us to answer the questions which are posed by veterans and to get first hand -- if you haven't been able to do so -- the stories that we hear.

And, I could furnish you with manifold documents, because in our hearings we request, if at all possible, that the witness present us with 15 copies of their testimony.

And, let me just take a statement from one, presented to us by a Monica Boeke, B-O-E-K-E, on behalf of

her former husband, now deceased, Lawrence Henry Boeke. This is a whole litany of his experiences with VA doctors, private hospitals, and doctors, no one or none of whom were able to give him any relief -- any answers.

The significance of his case should not be lost, in light of what is contained here on page 4: "As revealed in the autopsy, almost nothing in his entire body wasn't affected by this poison, dioxin." And, yet, nobody knew what was wrong with this young man. He died at age 29, after suffering the shades of hell.

As an example of the coverage we have been getting in Illinois and the encouragement, I think you have been furnished with copies of the newspaper stories, all of which recite the testimony presented to us by Vietnam veterans. And, in almost every case, the comment is --.

"The VA has been disinterested in my problem. The VA has told me there's nothing wrong with me." Or, as in one case, one gentleman, a big, husky, Black, obviously well educated, a -- at least a former outstanding physical specimen -- Incidentally, he appeared before us in the Chicago hearing, then followed us to our Peoria hearing because he wanted to re-emphasize what he had told us. He was wearing a knapsack over his shoulder when he was called to appear. We take them in the order in which they

register to appear before us.

He said, "yes, I appeared before you. I don't want to reiterate what I told you before, but I want to prove to you what has been my negative experience with the VA and the doctors available to me." He proceeded to empty his knapsack. And, I can't tell you now whether it was 25 or 35 vials, jars, tubes, bottles, most of which, according to him, were for the same thing -- the same type of medicinal placebo, but none of which did him any good.

I don't know that he was totally typical, but here is a man who needs our attention, ladies and gentlemen. He needs the sustenance and the support of your group, of the VA, and the medical attention that should be his rightful due, without his having to plead for it.

We've had testimony from a simple one page statement of"where I served, how many times I was sprayed;" to complete documentation of many pages. But, the recurring threat is health problems, from the most elemental of chloracne, to very complex of numbness -- unexplained, undefinable, untreatable, mental depression and/or fits of rage -- uncontrollable; headaches; children with defects.

This one widow has a three year old daughter who cannot speak or walk, obviously severely, physically

and mentally handicapped. But, nobody seems to be interested in her problem or what was the problem of her husband's life.

I congratulate you. We want to be helpful and supportive. And, I repeat, we're not here to really criticize, except to say, don't let this drop. We in Illinois are not about to let it drop. We have been concerned for all too long about, what now we are willing to accept, has been a lack of commitment -- a lack of concern -- a lack of interest on the part of the national government, the Veterans Administration, for the well being, yes, the very life, of our Illinois Vietnam veterans, who really are typical of the veterans all over this nation.

Thank you so very much.

DR. SHEPARD: Thank you very much, Senator Berning. I really appreciate your coming here and bringing the concerns to us. As you may be aware, from the outset of my role in this whole issue, I have felt very strongly that one of our very important missions is to stay in close touch with the states' efforts, and, as you probably also know, there now are a number of states which have established Agent Orange Commissions.

Some of those individuals are frequent attendors at our meeting. I see Wayne Wilson is here; Ruth Leverett,

from New York State. Wayne is from New Jersey. I understand there is a Mr. Conroy here, now, from West Virginia. I just got a call from some folks from Massachusetts, and they have established an Agent Orange Commission.

I was recently in Harrisburg, Pennsylvania. Pennsylvania is now getting under way. I was privileged to be at the opening meeting of their new commission.

So, I think we have a reasonable track record of staying in touch with state agencies. And, we certainly commend your efforts, and wish very much to welcome you into that group of people with whom we have been interfacing over the last several years and months.

We particularly want to hear of cases in which your constituents feel that they have received less than optimum care by the VA. There's no question that when this Agent Orange issue first arose that there was a lot of misinformation, a lot of lack of information; and, so that, I'm sure that there have been instances in which veterans have been treated with, in certain circumstances, where physicians, based on the fact that their knowledge was scanty about this whole issue, appeared to have come across as being less than concerned.

We want to hear about those cases. I think that the record will show that over the years we have tried to fill in some of these information gaps. We have tried to

maintain a very close contact with our some 180 environmental physicians; and, we want to continue that process. And, we encourage you to provide any information to us that might be of help to veterans in Illinois.

I understand you have an appointment with Mr. Nimmo this afternoon.

SENATOR BERNING: That's correct.

DR. SHEPARD: The Department of Medicine and Surgery will be represented by Dr. Earl Brown, who is acting in the absence of Dr. Custis and Dr. Jacoby. I have provided him some written comments on your efforts, all of which are to be highly commended; and, on specific ways in which we can relate more closely with your Commission.

And, once again, I encourage your participation or any members of the Commission participation in these meetings. But -- but, more importantly, at any time that you feel we can be of help to you, we'd be more than happy to do so, and we would like to --

SENATOR BERNING: We'll furnish you with copies of statements where we feel there are significant differences. And, I'll be pleased to send you copies of this from this Monica Boeke.

DR. SHEPARD: Fine. Yes. I'd like to have the details of that case.

SENATOR BERNING: Thank you so much.

DR. SHEPARD: Thank you, sir. Now, we also are privileged to have a representative from the State of Minnesota, Mr. Jerry Bender; and, I'd like to call on Mr. Bender at this time to bring us the greetings of Minnesota.

MR. JERRY BENDER: Thank you, Dr. Shepard. It's a pleasure to be here for a couple of reasons. Not only it's always an interesting activity to match voices over the telephone with faces and also it's warmer here than it is over in my side of the room.

This Spring the Minnesota legislature responded to the growing Agent Orange concerns of Minnesota's veterans by passing the Agent Orange Information and Assistance Program. Under this legislation the Minnesota Department of Veterans Affairs, with the technical assistance of the Department of Health and the University of Minnesota and the State's Attorney General, will represent the interests of Minnesota veterans nationally in the Agent Orange issue.

On July first, I assumed the position as leader -- Director of that Program; and, I hope to be dealing with a lot of you very frequently in the future.

I have a copy of the Minnesota Agent Orange legislation that I'd like to have included in the record.

I'd like to briefly summarize it now.

The first and primary responsibility is to monitor the federal government's progress in resolving the Agent Orange issue; that is, looking over the scientific and technical studies that are being done, and also keeping a close watch on any compensation and medical care provisions that are passed.

The Act -- the Minnesota Act--also provides for a comprehensive review of all the scientific literature on Agent Orange. What I want to do is analyze this literature; summarize it somewhat, I hope, or else we'll be sending out a thousand pages to each veteran; and, trying to explain to the individual Minnesota veteran in the individual county just what it is that he can expect from Agent Orange.

The Department of Veterans Affairs, and specifically my office, will be the single point of contact for all Minnesota veterans dealing with Agent Orange. Minnesota's Vietnam veterans and their families who feel that they need some health counseling -- for example, genetic counseling, -- something along those lines -- can also look to our office for referral to the proper state organizations.

And, finally, the Act also provides that the Department of Veterans Affairs -- the Minnesota

Department -- can undergo very limited medical or scientific studies dealing with Agent Orange. Now, of course, we're somewhat restricted -- as everyone is -- by budgetary considerations from conducting too many studies.

As you might be aware, though, Minnesota assumed a fairly vigorous role early in the Agent Orange controversy, when it first began. Various veterans organizations, in cooperation with the Department of Veterans Affairs, the county service officers in each county in the State of Minnesota, and also private industry, conducted an Agent Orange Outreach Program, that resulted in over 7,000 out of approximately 55,000 Minnesota veterans going into the Veterans Administration, and taking their Agent Orange exam.

It's my hope that I can maintain the momentum of that movement, not only in the Agent Orange field, but also in the research field, somewhat. I hope that we can supplement your efforts there.

One research project that we're presently considering now deals with the psychological and social functioning of Vietnam veterans, as a function of both objective measures of exposure and also complaints of exposure; that is, we want to see possibly if a veterans worries about being exposed to Agent Orange might manifest itself in some sort of psychological problem as measured,

for example, by the MMPI -- the Minnesota Multiphasic Personality Inventory, which is a standard psychological tool, and also by various objective measures of psychological functioning -- how well you're employed, whether there are any alcohol - chemical dependency problems -- something like that.

This study that we're considering is an extension and an offshoot of an earlier study conducted on about a hundred Minnesota vets that had taken the Agent Orange examination in the state. Dr. Gregory Korgeski, of the University and also the Veterans Administration, conducted this study as part of his degree program to become a Ph.D.

So, we're optimistic that some good can come out of this study. We hope to expand it to about three or four hundred veterans, depending on how many are willing to go through this extensive battery of tests.

In talking with members of other state organizations, I've come across two issues that I think the state organizations should immediately address. One is the issue of the coordination of all the state Agent Orange activities; that is, given the wide range of statutory responsibilities that we have, and further, given the limited budgets of the commissions, how can we best manage and coordinate our activities so that we can

essentially get the most back for the buck.

In other words, how can we avoid doing studies over again? How can we avoid needless repetition? Well, since I asked the question, I don't have to answer it at all. What I'm doing is soliciting responses from other state organizations. And, I hope if you have any ideas along this line, as indeed Ruth Leverett and Wayne Wilson have also mentioned, we can get together sometime; perhaps, come out with a newsletter, compare statutory responsibilities, and see if we can't avoid needless duplication of effort.

Another issue that I think we need to immediately address is the proper role of all of the state commissions, vis-a-vis the federal government's activities, here; that is, how best can we supplement and complement and support, and sometimes criticize the activities of the federal government?

As an example: The University of Minnesota has extensive program investigating twins. You might be familiar with this long term program. I think, for example, the University of Minnesota, through the efforts of the state commission, could also very nicely compliment the twin study that people are considering.

Also, given the fact that we have over 7,000 Vets on the Agent Orange exam, we have an excellent basis

for whatever data base that is needed in commissions like this. And, I'm sure that each state has resources that are unique to the state; and, that can periodically compliment all the activities that we have.

And, I'd like to hear from any state commissions that have a comment of these topics. You can reach me at the Agent Orange section of the Minnesota Department of Veterans Affairs, St. Paul, 55155. Those are all the comments I have.

DR. SHEPARD: Thank you very much, Jerry. I really appreciate your coming. As Jerry has just briefly touched on, Minnesota was one of the early states to develop an outreach program; and, I think, was kind of the standard bearer in that effort; and, working with our VA hospital in Minneapolis, a large number of Agent Orange examinations were performed in a relatively brief period of time. And, the hospital did really gear up to accommodate this sudden influx of applications for the examination.

I think it went very well. I hope that other examples may be forthcoming, of that close cooperative effort.

Jerry also touched on an area that I think is very important, and that is for we, here in the central office, to -- to be available to various state

commissions which are mandated to conduct various studies.

And, we have some good examples of that: New York State, which was one of the early -- one of the first states to get organized in terms of conducting a study -- has been kind enough to involve us in some of their work. And, there are some important studies -- cooperative studies -- that are underway with the VA and the state of New York.

We have been available, as I mentioned earlier, to consult with states, pointing out what efforts are underway, both within the VA and other elements of the federal government, so that the state activities will not be either disruptive or overly duplicative, but complimentary. And, I think that effort has been useful.

I think that,specifically, the ability of states to identify their Vietnam veterans and to -- to get current mailing addresses is one area that is very useful. It's often difficult to -- to know exactly who in your state is actually a Vietnam veteran and where he is today. Some states have paid bonuses to Vietnam veterans shortly after their return; and, although that is a good data source, the mobility of our population today indicates that people tend to move around. And, so that it's very helpful to have current addresses.

As our own studies go forward, I'm sure it will

be very important to solicit the aid of states in attempting to locate -- subjects. So that -- although we -- we hope to get some help from the Internal Revenue Service, there is some statutory authority to do that. I'm sure that the states could be a great help in locating Vietnam veterans who are -- who will be the subjects of various studies that we'll organize.

So, thank you very much. I appreciate it.

I would like now to call on our representatives from Service Organizations to bring to us any of their particular concerns. And, I apologize for not having welcomed Mr. Sypko as an official member of the Committee. Although he's attended in the past, he is now a full-fledged appointed member; and, we're happy to have you here.

Why don't we just go around the room and find out if there are any Service Organizations which have reports to make to us. Why don't we start with Mr. Thompson -- excuse me -- You're representing Mr. Thompson?

VETERANS SERVICE ORGANIZATIONS

MR. DAVE GORMAN: Yes. My name is Dave Gorman. Right, sir. I've -- like Mr. Sypko -- have just been appointed as an alternate member to this Committee by the Disabled American Veterans. This is the first meeting I have attended in an official capacity or in the

audience, itself.

I think just briefly I'd like to bring to the Committee's attention what we've been doing in the Disabled American Veterans -- as far as the Agent Orange problem is concerned. We've been, in our monthly magazine which has a circulation of about 1.5 million readers, we do have regular articles and updates on the Committee's reports and investigations, as well as our own updated versions of what we feel has been done and needs to be done on the Agent Orange issue.

Likewise, we employ about 270 professional men for the Service Organization nation-wide that are located in each and every VA regional office, some VA medical centers, and VA contact offices. We also keep them up to date as far as the -- what we feel -- by the Committee and recommendations of what we learned. We try to pass on to them, so they in turn can pass on to the veterans who are seeking our assistance.

We, at our national service legislative headquarters here in Washington, have received approximately 2,500 inquiries on a separate basis from concerned veterans on this Agent Orange issue. What we try to do is instill in them initiative to go ahead and file the claim with the VA for full compensation and medical treatment.

This is especially now in the legislation that

is enacted to allow this medical treatment to be given to Vietnam veterans claiming the exposure. We inform them by various pamphlets furnished by the Veterans Administration as well as our own publications information that we feel is useful in pursuing these claims.

Also, we strongly encourage they contact their local national service -- in which they reside to seek his advice, counsel, and guidance in what he needs to develop his claim or assistance -- for medical treatment.

I say this is the first meeting I've been to in this capacity. I've certainly enjoyed it so far. I found it informative. It's also refreshing to know that there are individuals like Senator Berning and Mr. Bender from Minnesota, who are actively involved at the state level with the Agent Orange problem.

I'd like to extend to both of these gentlemen and anybody else in the audience our total assistance and cooperation, if we can, either on a national basis or locally in our regional offices in your areas. Any kind of assistance we can provide, we will be happy to do so. Thank you.

DR. SHEPARD: Thank you very much, Mr. Gorman. You touched on something that I had intended to allude to earlier. But, at this point I won't spend a lot of time on it. But, just remind the members of the Committee as

well as members of the audience that the guidelines for Public Law 97-72, as they relate to Agent Orange,have now been fully promulgated; and this, in a nutshell is legislation that authorizes the VA to provide treatment to non-service connected veterans who appear at VA hospitals for conditions that they believe are the result of Agent Orange exposure,

with the exception of five areas or five categories of illness which, in the view of the chief medical director -- and this is provided in the statute, considered as resulting from exposure, and these are -- This provides a broad range -- or the authority to provide treatment in a broad range of conditions. So, the legislation is there; and, the authority does exist; and we have promulgated, as I say, the guidelines for -- for implementing that legislation.

Thank you very much. Mr. Sypko, what can you tell us?

MR. THEODORE P. SYPKO: As a Field Representative to the VFW, I have an opportunity to visit many VA hospitals in the mid-west and northeast; and, what I find in several hospitals are that under 10-10's they have questions that they tend to -- whether the veteran is Vietnam or Vietnam-era veteran, so they can keep track of what the Vietnam veteran population is so they can deal

with these veterans, which seems to be working very well.

They're getting a lot of veterans in for examinations, and they notify them of the results on time. However, some of the complaints that we're getting from the veterans are: Why is the study taking so long? And, why aren't the veterans being updated on the progress of the studies? And, this is one of our great concerns. We hope that these answers are given soon.

DR. SHEPARD: Okay, fine. We have just recently completed at least the first step in developing a follow-up mailing list to anybody who has come in for the Registry examination, so that we now have the opportunity of contacting people and providing them with the update.

Up until this time, that has not been a very easy effort. I mean -- we didn't have an automated mailing list of everybody in the Registry. We now are close to having that; so, we will be able to provide to any Vietnam veteran, who at least has come into the examination, follow-ups. We are presuming that, as a minimum, the people who are most interested and are most concerned are, at least, fairly largely represented in the Registry.

If that's not the case, then we certainly will look to the states and the service organizations to provide us with names and addresses of individuals who have expressed an interest in receiving more information

than they apparently are, if they're not already in the Registry. For the most part, those people in the Registry will have their names and addresses on an automated file in central office. That's, I think, a fairly major step forward.

Thank you. Fred, what can you tell us from PVA?

MR. FREDRICK MULLEN, SR.: Well, nothing particular from PVA; I just have a few questions of the Administration.

In 1968 the Mid-west Research Institute, in 1974 the National Academy of Sciences, in 1981 the General Accounting Office, and also in 1981 JRB in their literature review recommended further studies into Agent Blue. The Administration went out for proposals. Ten were accepted, and awards to various hospitals have been assigned.

Since at least 5 or 6 proposals were received in regard to Agent Blue, and since the Administrator had committed the Administration to the study of Orange and Blue, I'm wondering why not one of the Agent Blue proposals was accepted. And, in regard to Dr. Irey's comments regarding the incubation period of carcinomas or cancers and the generally accepted knowledge that both organic and inorganic arsenicals are carcinogenic, I'm wondering why the Administration does not follow through on any of the Agent Blue proposals.

And, I'm wondering also if you intend or if the Administration intends to rely on the Agent Blue Monograph as prepared -- or to be prepared by Dr. Hood for results on Agent Blue; or, whether that monograph will be used to determine if additional studies on Agent Blue are necessary.

DR. SHEPARD: Okay. Let me answer at least one of the questions that I can relatively readily; that is, the matter of the failure of the central office to have funded any studies on Agent Blue.

The Merit Review Process is one which looks at the scientific merit of a proposal; that is the way the study has been put together

In other words, the Merit Review Process did not decide to fund a certain number of studies on Agent Orange, a certain number of other studies on Agent Blue. They didn't divide them up into categories.

Solicited projects were all reviewed for their scientific merits, without regard to the specific Agent that was to be studied. So, there was no -- I'm sure -- there was no intent to systematically eliminate the Agent Blue proposals. It was for reasons -- not know to me personally, but part of the Merit Review Process. The scientists who did review these projects looked at them from the point of view of their

scientific merit.

We were disappointed -- very disappointed that some of the Agent Blue proposals were not deemed to be worthy of funding. And, that isn't to say that there isn't an opportunity to revisit those studies and provide some consultation to the researchers who have submitted these proposals, and try to improve the protocols or the proposals and to bring them up to the level of scientific excellence for funding.

We have discussed this, and we'll be looking at ways to do that. There were relatively limited dollars for this particular effort in this fiscal year; so, there were some fiscal constraints, although there has been a fairly large amount of money -- I think some 2 million dollars in that particular group of studies over the next three years.

But, we are concerned, let me assure you. And, we will be looking at the whole issue of Agent Blue. In the matter of the monograph, that will be a summation of existing information, and the conclusions, and the beliefs of the author of the monograph, in consultation with other experts in the field. It will not attempt to replace, but rather to summarize and bring to the attention of the scientific community what the real scientific issues are, related to --

You had another question that slipped my mind?

MR. MULLEN: Well, I was wondering if you were going to rely on the monograph results to make a determination of whether further studies in the Agent Blue should be done?

DR. SHEPARD: I should certainly hope. I haven't been intimately involved in the details of the production of the monograph. But, I would certainly hope that the monograph would have as part of its thrust a recommendation for further research efforts. I think that would be an appropriate area to address.

MR. LeVOIS: Not only that, but I think part of the rationale for that particular monograph is it stimulates not only interest but also a better understanding of exactly what the areas of further research would be.

I hope that the monograph will provide us with another round of proposals from the field, and a group of better quality.

MR. MULLEN: I just have a couple more questions. First: At the outset here I mentioned four different groups, the General Accounting Office, Mid-west Research Institute, National Academy of Sciences, and, of course, JRB.

Were any members of the Merit Review panel aware

of the recommendations of these four groups?

DR. SHEPARD: I can't answer that because I wasn't part of that deliberation. Al, do you know offhand?

DR. YOUNG: No, sir. I don't.

DR. SHEPARD: Is Dr. Kinnard here? Matt, did you hear the question?

DR. KINNARD: I didn't hear the question.

DR. SHEPARD: Okay.

Did the Merit Review Process involve information that came out of these four studies that Fred Mullen alluded to? I presume -- you know -- I'm just guessing that anybody tasked with the -- with the job of -- of reviewing research proposals would have more than just a passing acquaintance with what research efforts has been both conducted and have been recommended by other scientists.

So, I just have to conclude or presume that, certainly, some members of Merit Review Committee were fully cognizant of these reports that you alluded to, but I can't say that for personal knowledge.

DR. KINNARD: May I hear the question once more, Mr. Mullen?

MR. MULLEN: I mentioned the Mid-west Research Institute, General Accounting Office, National Academy of Sciences, and, of course, the VA's own contracted literature review, which was done by JRB Associates. All

four of these groups or agencies had recommended--indeed some had even advocated--further studies into Agent Blue or organic arsenicals. I was wondering if any of the members of the Merit Review panel, who studied the research proposals, had any insight or any knowledge as to these recommendations or advocated studies?

DR. KINNARD: Yes. They were cognizant of these recommendations. However, let me review briefly how the studies got started in the first place.

These research studies were strictly solicited voluntarily by Medical Research Service in an attempt to provide baseline information on the toxicology, pharmacology and biochemistry of Agent Orange which apparently now is unavailable. The panel was constituted on the basis that they were recognized scientists who were experienced and knowledgeable in the area of the toxicity of both organic and inorganic arsenicals as well as the toxicity of Agent Orange.

One additional point I'd like to make is that the scientists who reviewed these projects were non-VA scientists and non-DOD scientists. That was one of the criterion that we adhered to in order to avoid bias or anything of that nature in reviewing the proposals.

Now, in terms of their being aware of the recommendations made by the four groups previously

mentioned, I can say that they indeed were aware of the recommendations.

But, to underscore what Dr. Shepard said, the projects were all judged on the basis of their scientific merits. Two of the Agent Blue projects were approved but were not approved at a level that could be funded, based on the current funding policy of the Medical Research Service.

MR. MULLEN: So, therefore, the commitment of the Administrator to do further studies in the Agent Blue is not completely nullified by the Merit Review panel's assign -- or non-assignement of awards for studies of Agent Blue at this time?

DR. KINNARD: Let me respond to that question by saying that all 36 projects -- Agent Orange and Agent Blue projects -- have been reviewed and summary statements have been prepared and typed. The summary statements have been mailed to the principal investigators, and they have been encouraged to amend their proposals, and resubmit them for future review and funding considerations.

MR. MULLEN: Okay. Thank you.

DR. SHEPARD: Do any other members of the Committee have any responses to any of the three speakers who just -- I forgot to call on you all -- any repsonses, reactions to anything that they have brought to our attention?

Okay. Dr. FitzGerald?

DR. THOMAS J. FITZGERALD: Most of the organizations have just gotten through their national conventions. And, from the personal contacts at the convention, there is still a concern out there concerning Agent Orange, as you well know.

I think this concern still focuses in on two areas. And, one is the concern about genetic malformations and unexplained illnesses. And, I exhort the Veterans Administration to approach both of these as their major concern right now while the studies are undergoing.

These people need reassurance. Reassurance is essential in order to overcome some of the biases that you're getting out there right now concerning what you're doing. We who have been exposed intimately to what's going on are satisfied as to what's going on and the purpose as to why you're doing it and why it's taking so long.

But, in the interval in between, from a humane basis, we have to reassure these individuals. They are exposed to the claims that are made in the media, claims made by individuals about the adverse effects, and they have no way of knowing the truth or the incidence of what's occurring here.

What you're doing about getting in touch with

these people is one good approach. But, at the local hospital level, they know these individuals who have problems that have surfaced at their individual hospitals. From a local hospital level, if they could key in on these individuals, I think that a lot of this adverse publicity will be done away with.

As far as the concern that Senator Berning made about the concern of the Veterans Administration and the examinations that they're receiving at the hospitals, we too have gone out to the individual hospitals. We have representatives there on a continuing basis. And, one of the things our representatives do is to examine the quality of the examination that the veteran is receiving at the Agent Orange examination.

We have previously expressed to Dr. Shepard some of our concerns about follow-up and notification of the individuals. This was taken in action by the Veterans Administration and these veterans are now receiving letters.

Again, I stress the fact that as these people have examinations, some time spent with them in reassurance at that time will also be very beneficial.

There are, unfortunately, incidents that occur in any large populations, such as the case that you've probably referred to. But, that has not been our experience as far as representatives at the hospitals are

concerned. Certainly, the large majority of the veterans that are going through the hospitals are satisfied with the examination that they're receiving. They're more satisfied when they get a follow-up concerning the results of that examination.

DR. SHEPARD: Thank you very much, Dr. FitzGerald. I would like to, first of all, express my appreciation for your kind words about the system that we put in place. And, for those who are aware of it, basically, any veteran coming in for the examination: Two things are suppose to happen that flow from the examination.

First of all, there is to be an exit interview, wherever possible by the environmental physician, with the veteran and the environmental physician. There is a face-to-face, verbal dialogue, which enables the veteran to express any concerns to the environmental physician, either about the nature of the examination or the results of the examination, or other concerns that were not specifically dealt with in the course of the examination -- such as the likelihood of fathering children with birth defects.

That is a program that was established. We hope that it is going forward effectively. One of, perhaps, the things that we need to tighten up is on a monitoring system of how that program is going. The

direction is out there. The policy has been established. To the extent of our ability to determine, -- we have a pretty good feeling that it is going forward well. But, we don't have a formal monitoring system for that, and I think that's something we can look at.

So, that's one thing. There is a face-to-face interview with the environmental physician, or in his absence with a physician knowledgeable in the area of Agent Orange issue.

The other is a letter that you referred to, which is a follow-up letter sent out by the hospital to each veteran, giving the results of the physical examination and the laboratory studies -- and, not only the results, but the significance of those results, to the extent that they can be described.

I hope that that process is going along well. As I say, I think that's been reassuring to many veterans.

On the matter of the birth defects concern: That is always and remains a major -- a major concern. Unfortunately, Dr. David Erickson was not able to come to the meeting at the last minute. He's been a very faithful member of the Committee. And, I was hoping that he could give us an update as to the status of the CDC birth defect setting. I try to keep in close touch with Dr. Erickson;

and I can tell you that the pilot study for that effort has been completed. They are now into the full scale study. It's moving along very well.

They apparently have superb cooperation with the IRS in getting recent addresses. And, once the individuals are found or contacted, the cooperation has been excellent. They have a 90 plus rate of compliance with the -- with the request for -- for having the interviews. So, once the individual is contacted, they are able to get the questioning completed. So, we're looking forward very much to the result of that effort.

The monograph series, we hope, as Al alluded to, will provide another resource to our hospitals in order to provide sound scientific information.

There is still one other element I think that we need to think about,and,that is: Given a veteran who has children with birth defects, how can we reassure him that either he will or will not have a likelihood of having another child with birth defect; or, a veteran who has not had any children, what is the likelihood of having a child with birth defects?

That's a very, very difficult question to answer, as I'm sure you're aware, because so much about the etiology of birth defects simply is not known. I hope the monograph series will bring to light what is known and

serve as a basis of that guidance.

But, I agree with you, we still need to do a little better job by -- that whole area of genetic counseling, and how we hope to move in that direction.

Any questions for Dr. FitzGerald from other members of the Committee?

Now, I'd like to call on Mr. Hugh Walkup who represents the National Veterans Task Force on Agent Orange.

MR. HUGH WALKUP: Thank you. I have a few comments and quite a few questions that -- that I'd like to raise. We remain concerned that the pace of the studies and the answers that we've been looking for for a number of years -- and especially that several years since we've had an Act of Congress that called on the Veterans Administration to undertake this study -- that we're still in the position of trying to design the study.

We are concerned that several years after an Act of Congress called on the Veterans Administration to undertake this study, that we're still in the design phase; and that the design phase seems to be taking longer at every point, and that it's going to be a long time before we get to the point of having any answers about what's going on in Agent Orange, even though we've been asking those questions for a number of years.

We are very concerned about the pace of that; and, we encourage all expeditious speed to get us to the point that we all want to be. And, especially that whatever studies that we've got be designed towards an outcome of being able to tell us some answers about what really is happening to the people that we're concerned about, rather than -- than basic research that might help us design more studies or get to other places that might lead to some more interesting conclusions.

What we need right now are some things that give us some answers.

Our second concern is about the variability of local procedures, in terms of the exams, or in terms of the exit interviews, follow-up studies. There have been a number of changes; however -- especially, recently, but over several years; and, what's suppose to be happening in local VA medical center.

And, we found that the implementations of circulars of policies in local medical centers varies a whole lot, even within the same region; and, that in some cases people have not received the circular or haven't found it or haven't implemented it. And, it has taken a fair amount of effort on the part of Veterans Organizations and local groups to encourage the local

administrator, when we've found out what the policy is suppose to be; to find the circular for them, to get the procedures underway.

And, I strongly encourage the monitoring staff that you're talking about, because I do believe that monitoring responsibility rests with the Veterans Administration to make sure its policies and procedures, and especially the circulars, that are the outcomes of federal law, get implemented at the local level. And, merely hoping that those things happen is not an effective way of making sure that policies do get implemented there. That's important to the veterans who show up -- very much so.

Another area of variability that we found is in the distribution of the new leaflets that, in some places only one of the three new leaflets is being distributed, some together with the old ones, some without the old one. If there is a policy about which people are suppose to get, then it probably would be good for everybody to have the same information.

The new green leaflet appears to not have some of the information that was available in the orange leaflet before, about some of the specific, possible health affects that have been alleged to be related to herbicides. So, we would encourage that, as this is

distributed, that the previous leaflet also be distributed at the same time, so that people can have this thorough information about what's going on as possible.

I was very pleased that the Secretary of Veterans Affairs from Australia was able to be here today; and, I think there was some very instructive things that came out of his presentation. One is the apparent impact of judicial review or just that their system is different, and that the outcome of that has been a very different burden of proof from that which exists in the United States.

That burden of proof has been an especially heavy burden for veterans who cannot fund multi-million dollar studies on Agent Orange, and have had the track record and success rates so far have encouraged the Veterans Administration to undertake those studies on their behalf. It's been impossible for them to prove their case lacking those studies.

And, their presumption that's been made in Australia, that lacking that proof, that the burden should fall on the government, rather than on the veteran, seems to be a more appropriate way to handle that.

Another issue that I wish we had been able to follow up with the Secretary and I hope you might at another time -- is a recent study that was --

that's apparently created a fair amount of controversy in Australia that was undertaken by a Dr. Malcolm Bar. His study-which was apparently fairly preliminary or at least a lot of discussion with -- within the scientific establishment there -- purportedly came up with some indications of neurological affects of Agent Orange and was attempting to relate some of the systems of post-tramatic stress disorder to Agent Orange.

And, not being an expert in that area, I cannot analyze that, but I think that would be something instructive for to be able to find out more about.

I do have a copy of a local press report on that study, which might give you some of the background information on that.

DR. SHEPARD: All right.

MR. WALKUP: There were several questions that I had coming up from some of the presentations that have been made so far. One is about the request for proposal for the pilot study. Am I to understand that within the next three weeks, the protocol will be completed and the time that that is completed, we also will be having a design of the sample;and, that would mean within a month it would be possible to decide upon the protocol, the sample design, and to issue an RFP

scheduled around those, and so that people, then, within the next month would be -- would be responding to that? Is that correct?

DR. SHEPARD: Not exactly. We have sort of targeted that ourselves to the end of October to get the RFP out. It may fall within that time frame, but we certainly anticipate having the RFP out by the end of October.

We want to give perspective contractors plenty of time to prepare their proposals. I think one of the problems that we faced with the UCLA contractor was that we imposed an unrealistic time tables on UCLA, and that was evidenced by the fact that they requested adequate extensions of time, from time to time, which were appropriate.

So, we want to give this contractor or this group of contractors an adequate period of time in order to respond. We're targeting a three month period of time to come in with their proposals.

We think that, hopefully, by the middle of February we'll be able to award the contract. Now, these are tentative time tables, but that's kind of the ball park that we're looking at.

MR. WALKUP: What length of time are you projecting that it will take once the RFP is -- or

once the contract is awarded for the study to be completed?

DR. SHEPARD: In 18 months and 2 years.

MR. WALKUP: So, that will get us past 1984 or 1985?

DR. SHEPARD: Early '85.

MR. WALKUP: What standards of proof will be required out of the study for us to be able to answer the questions that veterans have about what is Agent Orange doing to us? Is there in the RFP -- I would assume that there'd be some specific tests which would be of interest from a policy standpoint to say -- say a test of statistical significance or two times the incidence against a control group, or something like that. What are going to be our standards in 1985 for evaluating the results of the study?

DR. SHEPARD: Okay. The pilot study, as I'm sure you're aware, will be aimed at determining the feasibility and the appropriateness of the protocol. In other words, that's really the test -- the purpose of a pilot study is to test protocol.

In order to do that, we'll try and have a protocol for the pilot study as close to the protocol for the full study as possible; that is, to the extent that we can anticipate how the full scale protocol should be. We will have the pilot study protocol as closely matched

to that as possible.

Of course, we're matching -- testing that protocol, so there'll be an opportunity to revise the protocol before the full scale study, based on the experience which is disclosed from the pilot study.

But, we normally -- scientists normally do not look at the results of a pilot study as a microcosm of -- of the full study, in terms of the results of that study as it relates to health outcomes. The pilot study is more for the purpose of testing methodology -- and arriving at the statistically supportable conclusions.

So, it really won't be until the full study is completed that we'll have the final answers, as far as this particular study is concerned.

Now, in the meantime, I just want to assure everybody that we're not going to be without any answers until that long time in the future. As you know, the Ranch Hand study is well underway. We hope to have some results from that -- from that study within the next year to year and a half. Some early results in the mortality figures should be out in a couple of months.

The CDC Birth Defect Study is another major concern. It should be out by the end of '84.

The Twin Study, if it gets funded appropriately, will also come out of that same general time frame.

So, there are -- there will be a number of studies that will shed light on various facets of the whole issue prior to the time that our full blown study is completed. So, there will be a kind of a continuing events --

MR. WALKUP: Do you see a point at which some policy decisions could be made coming out of those interim studies that you're talking about? Have we got any defined check points to say, now, here's when we'll know about this?

DR. SHEPARD: Well, yes. I think certainly, conceptually, that -- if the Ranch Hand study, for example, comes out with some very persuasive evidence that there are some specific health problems that have resulted from exposure to Agent Orange, that there'll be an opportunity to develop recommendations to Congress for whatever that might require.

So, that, at any point along the way, I think there will be the opportunity for new policy development.

MR. WALKUP: Could you flesh out the rest of that time line, then, once we get into the -- the results of the pilot study, what happens next and when do we have the complete study?

DR. SHEPARD: Well, that's a little bit difficult to predict at the present time. I would hope that if the

pilot study goes well, and we don't run into any major problems with regarding exposure or cohort selection or cohort cooperation; we don't have a good feel yet as to what we might expect in terms of the rates at which people will be willing to be a part of the study.

We have two -- we hope -- reasonably good indicators in that the Ranch Hand study and the CDC Birth Defect Study a very high rate of compliance. Whether that same compliance rate will be reflected in our study, it's a little difficult to predict because the situation --

But, assuming that we have a high compliance rate, and that will be a key element as to whether or not we will be able to go the full study. Assuming that we have a high compliance rate, and assuming that the protocol comes out reasonably well, from the pilot study, that probably a period of three to four years will be required for the full blown study.

Now, that's assuming that we're going to examine some 6,000 veterans in each of three cohorts. There's been some question about whether or not we have to have such large samples. So, that's why I'm saying it's a little difficult to predict. The time table will relate to the size of the cohorts, and also whether or not this study will be done with a contract, or in VA medical